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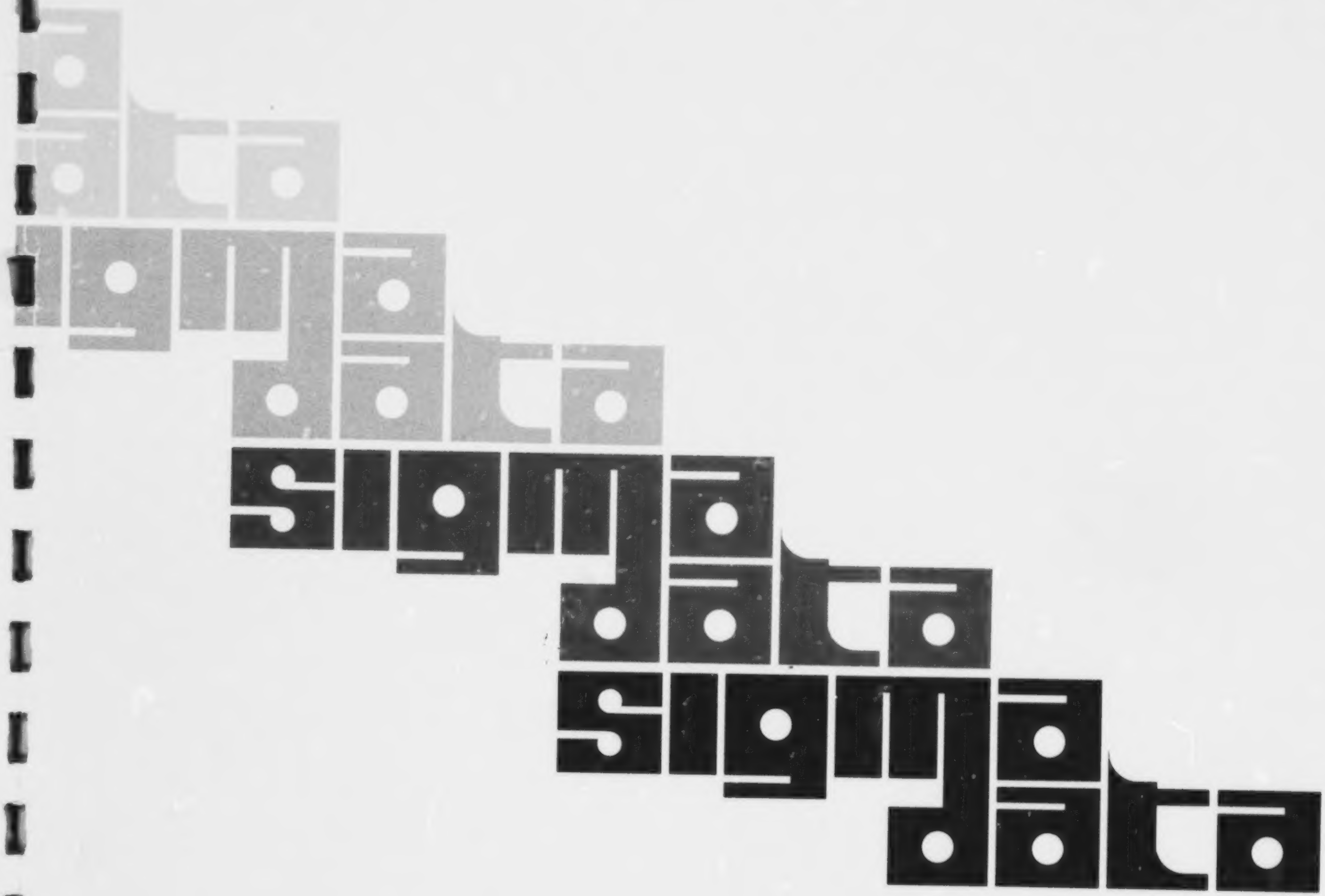
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GENERAL DESIGN REQUIREMENTS
FOR A
CHEMICAL REGULATIONS AND
GUIDELINES SYSTEM

FINAL REPORT

PREPARED FOR
COUNCIL ON ENVIRONMENTAL QUALITY
ENVIRONMENTAL PROTECTION AGENCY
FOOD AND DRUG ADMINISTRATION
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
CONSUMER PRODUCT SAFETY COMMISSION

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EXECUTIVE SUMMARY

A Regulated Chemicals System, or a Chemical Regulations and Guidelines System, was recommended in the Mitre Report as one of the core components of the Chemical Sustances Information Network (CSIN). Under a contract with the Council on Environmental Quality and the Information Exchange Group of the Interagency Regulatory Liaison Group, Sigma Data has conducted a study of the general design requirements for implementing such a system.

Potential users of information pertaining to regulated toxic substances in the Federal community and in the private sector were surveyed in order to identify the primary user requirements. Based upon this survey, Sigma Data designed an ideal, proposed system to meet the specified informational and operational requirements. These included chemical-specific access, a differentiation between chemcial use and/or application, and an awareness of current regulatory activity.

An assessment was made of relevant, existing systems to determine the extent to which their capabilities might be enhanced or adapted. Following an analysis and evaluation, three commercial systems were identified which met the established criteria: Information Handling Services; Capitol Services Inc., and the Environment Information Center, Inc. These systems were evaluated with respect to their current resources as well as their potential for meeting additional requirements. An implementation option for developing a wholly public data base was also conceived and presented.

All of the implementation work plans suggest a computerized CRGS can be operational within two years from a start date at a maximum cost of $210,000. Federal laws and regulations, court decisions, state regulations and laws, NIOSH Criteria Documents, recommended standards, and international guidelines are recommended for inclusion.

In order to facilitate linkage among components of the CSIN, provision must be made to maximize the functional interface. This can be best effectuated at this stage through the use of the CAS Registry Number, a listing of the chemical name identification in the Chemical Structure and Nomenclature System, and the coordination with the subject categories used in the Chemical Data Bases Directory.

1.0 INTRODUCTION

1.1. Background

The Toxic Substances Control Act (TSCA) mandated the Environmental Protection Agency (EPA) to comprehensively assess the hazards associated with chemical substances. Other agencies, such as the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC) are authorized to regulate only those chemicals which fall into their particular jurisdictions. This jurisdiction is usually determined according to the state of development of a chemical (e.g., production, transportation, disposal) or its application (e.g., pesticide, preservative). TSCA permits a broader consideration than just occupational or consumer hazards by including the spectrum of health and environmental effects. Section 6 of the TSCA specifically recognizes the regulatory authority of EPA in regard to hazardous chemical substances and mixtures, whereas Section 25(b) requires the Council on Environmental Quality (CEQ) to coordinate the means for the storage and retrieval of information pertaining to those substances. The legislative mandate for establishing information systems responsive to agency needs is, therefore, clear.

Recognizing that there were grounds for a coordinated effort among EPA, FDA, OSHA, and CPSC, due to overlapping jurisdictions concerning chemical substances, the Interagency Regulatory Liaison Group (IRLG) was established. The IRLG was charged with reviewing the "common requirements and functions of the four agencies as they pertain to the regulation of potentially hazardous and toxic substances."[1]

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[1] Report on Progress of the Interagency Regulatory Liaison Group July 22, 1977, p. ii.

It was simultaneously authorized to initiate "a process by which present interagency cooperative effort can be improved, augmented or designed as necessary."[2]

Several functional working groups were created within the IRLG, one of which was the Information Exchange Group. Anticipating the large volume of data to be generated in response to new policies and legislation, this group was directed to consider current information systems and their suitability for meeting future requirements.

The Mitre Technical Report, MTR-7558 (June 1977) which analyzed the user requirements and existing information systems for a Chemical Substances Information Network (CSIN), concluded that a centralized system was needed to facilitate access to, and awareness of, relevant federal, state, local, and international regulations and standards on a chemical-specific basis (MTR-7558,p.4-30).

The general user activities identified by Mitre were divided into three functional groupings: Category I, or Hazard Identification/Prioritization of chemical substances; Cateogry II, which covers Hazard Analysis, Monitoring/Testing, Preparation of Decision Packages, etc., and which essentially involves risk assessment; and Category III, which incorporates Category II, and Research/Development. The supporting documentation generated from Categories II and III, in particular is a necessary component of regulation development.

After reviewing a number of existing data files, the Mitre report concluded that there was no central source from which all the relevant standards and regulations on a specific chemical could be extracted. Similarly, there was no source from which responses to queries from the public or industry regarding compliance could be serviced. Mitre recommended, therefore, that a study be conducted to determine the general design requirements for implementing such a system within the CSIN.

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[2] Ibid.

1.2 Approach and Scope

A Chemical Regulations and Guidelines System (CRGS) was conceived to facilitate access to all relevant standards, regulations, and guidelines through the capability of retrieval on a chemical-specific basis. Both industry, the regulatory agencies, and others would then have a file from which a current awareness of standards and regulations, both proposed and in effect, would be available. The initial task involved the specification of the general system objectives in order to conduct meaningful interviews with the appropriate user groups. The representatives to the IRLG Information Exchange Group suggested personnel from within their respective agencies who would be best suited for addressing the user requirements. In addition, Sigma Data identified and interviewed potential users in other organizations, such as union and industrial trade groups, in order to determine their specific information needs. No attempt was made to be exhaustive, but rather, the concern was more to establish contact with representatives of potential users in the private and public sectors, and to incorporate their particular requirements, if any, into a proposed system.

These information needs may be generalized as:

- access on a chemical-specific basis
- keeping up-to-date on new regulations
- interagency awareness of regulatory action

- awareness of anticipated action (proposed regulations)
- awareness of standards and guidelines, and not just the law

Following a detailed analysis and assessment of the user requirements, with due consideration given to the scope of subject input and priorities for inclusion, an ideal system was proposed which encompassed conceptualizing the flow of information. This was broken down into the functional areas of:

- Data Collection
- Data Preparation
- Maintenance and Update
- Search and Retrieval

Before recommending implementation alternatives or strategies, Sigma Data conducted a detailed evaluation of existing systems to determine the extent to which user requirements were already being met, as well as some consideration as to how they might conceivably be enhanced. Several of the existing sources which cover the proposed subject scope are commercial firms, and some discussion is necessary with respect to the problems of marketing a government-supported database in competition with private enterprise. The implementation options take into account considerations of personpower, resources, and time. The advantages and disadvantages of each are thoroughly investigated and assessed in the final section of this report.

2.0 USER REQUIREMENTS AND OBJECTIVES

2.1 General Systems Objectives

Before delineating the specific users and their information needs, the Chemical Regulations and Guidelines System under consideration should be further clarified. For the purposes of this study, the system has included those regulations and guidelines which fall into the realm of federal, state, international or foreign authority. In addition, recommended standards which do not have legal effect will be considered as part of the system.

It is anticipated that the next few years will see a sharp upswing in the number of rules and regulations promulgated which apply to toxic chemicals. TSCA empowers EPA to require reports on the manufacture and processing of new and existing chemicals, on production levels for selected substances, and health and safety testing documentation. In addition to these specific stipulations, other supportive information will be needed to make decisions regarding use application, labeling, packaging, and distribution. In each case, a decision rendered by an agency which is intended to have the force of the law, must appear in the Federal Register for public notification. Other sources, such as court decisions, also impact on the legal and safety aspects of chemical substances and a means of including them must be formulated as well.

Given the various sources of regulations and guidelines, it is also necessary to examine the current and projected volume of regulations. In April 1976, the Office of Toxic Substances at EPA developed a Summary Tabulation of

Selected EPA Activities Concerning Toxic Chemicals in which 186 substances or chemical classes (excluding radioactive materials) were classified according to their status. For example, dieldrin is regulated under the Clean Water Act, the Safe Water Drinking Act and the Pesticide Laws (FIFRA, FEPCA and FDCS). This relatively short document gives only a brief glimpse at laws, standards, or reports in progress with the emphasis on current or imminent regulatory activities. The NIOSH Registry of Toxic Effects (1976) lists 21,729 substances, an increase of 5,228 over 1975. These are not all regulated, of course, but it is indicative of the dimensions of the chemical substance universe. OSHA, in conjunction with NIOSH, has established the Standards Completion Program which encompasses 400 substances. Estimates of the number of chemicals in commerce range from 50,000 to 100,000. The Toxic Substances Candidate List includes over 30,000 chemicals whereas the Office of Pesticide Programs has registered an estimated 35,000 substances. FDA has thousands of chemicals registered as drugs, food preservatives, food additives and cosmetics. The CPSC has a much smaller regulatory domain in comparison, but it is nonetheless relevant. It is fair to conclude that the volume of substances suggests a corresponding volume in regulations.

There are then two general objectives which can be stated: (1) to bring together the laws, regulations, and standards pertaining to chemical substances, and (2) to provide a means of inquiry by which information on proposed or promulgated standards on individual chemical substances or classes of chemicals can be accessed.

2.2 System Users

To gain a clear understanding of the user requirements, personal interviews were conducted with individuals within the four IRLG agencies, as well as with selected representatives of other organizations. Due to time and distance limitations, some reliance was placed on the Mitre report, Vol. II, for stating some of the user needs.[1] Telephone interviews were also sufficiently informative in other instances. A list of the individuals interviewed and their respective organizations is presented in Appendix A.

During the interviews, the individuals were asked to describe their present methods of staying informed about regulations and guidelines, or where applicable, of responding to inquiries regarding a specific chemical. In addition, the information sources currently used to satisfy those needs were identified. Potential users were asked to comment upon the development of a centralized file for regulations and guidelines, what should be included, as well as the preferred method(s) of accessibility. Based upon those expressed needs, a general design for a proposed system could then be constructed.

2.2.1 Environmental Protection Agency - EPA

Within the EPA, there are two offices which are primarily concerned with chemical substances, the Office of Pesticide Programs (OPP) and the Office of Toxic Substances (OTS).

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[1] Bracken, M., etal, Chemical Substances Information Network, Vol. II: Appendices. McLean, Va.: The Mitre Corp., Metrek Division, June 1977. Contract No. CEQ 7A010

Under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq*.), the Office of Pesticide Programs is responsible for the registration, classification, and use of chemicals as pesticides in the environment. Whenever an application for registration of a pesticide is made which includes either a new active ingredient or a changed use pattern, a notice must appear in the Federal Register. If the application is denied, notice of such action must be published there as well. As part of the registration process, the product must also be classified for general or restricted use. While these actions are not regulations in themselves, they do indicate the jurisdiction under which OPP operates.

In the process of evaluating pesticides for registration, OPP has exercised its regulatory authority by taking action on chemicals proven to be harmful, regardless of their use, such as DDT. In order to respond to inquiries regarding the statutory and regulatory law pertaining to pesticides, OPP currently has three offices supporting that function: (1) the Public Inquiry section (2) the Congressional Inquiries Section, and (3) the Federal Register Section.

The Public Inquiry Section responds to questions from groups such as farmers, students, and the general public in all areas of pesticides, ranging from information about registration to concern for health effects and tolerance levels. Many of their inquiries are satisfied by mailing out warning labels for a product, however, a subject file is maintained which includes correspondence, RPARS,[1] reports, and journal articles related to specific chemicals.

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[1] Rebuttable Presumption Against Registration - issued by the OPP to indicate that its evaluation of a specific product has found the product to exceed certain risk criteria. The registrant and other interested parties are then requested to submit additional data and/or evidence to rebut the evaluation.

In addition, all the pesticides are divided among Product Managers who are assigned certain chemicals for which they are responsible. Technical questions as well as those pertaining to the regulations are referred to them. It is estimated they receive 20-30 inquiries per week.

The Congressional Inquiries Section is oriented towards Members of Congress or their staff, state government officials, or other official government personnel. Questions range from why a pesticide was removed from the market to the current status of a product under consideration for registration. Relevant Federal Register documents are on file, mainly in chronological order, but there are some subject files. Generally, inquiries are not of a technical nature.

The Federal Register Section receives inquiries from small business and industry. An extensive chronological reprint file on the Federal Register is maintained and many of the incoming questions pertain to regulated substances. A simple index to this chronological file is posted but personal familiarity with the pesticide regulatory history seems to be an important factor in its usefulness.

Within the OPP, there is currently no mechanism for easily responding to questions about particular chemicals, except for those dealing specifically with registration, RPARS, or exemptions. While each division discussed above seems to function well, there is no apparent continuing dialogue on how to respond to similar questions. The functional division is based on the identity of the inquiries.

In discussions pertaining to desirable access points, it was suggested that the following be considered:

- Chemical and Class Name - Generic standards in OPP permit the comparison of currently regulated compounds with proposed compounds. As long as there are no changed uses, or no new active ingredients, a generic standard may apply. In other words, the registration of "like" compounds will not appear in the *Federal Register* .

- Document Identification - It would be useful to be able to differentiate between whether legal compliance is derived from a regulation or whether it results from a court action. In a similar vein, if standards (which do not have the force of the law) were included in the file, than it would be important to distinguish between them and those "items" which carry statutory authority.

- Functional Use - Often information is required on a specific use of a chemical substance, particularly what it is used to control. Thus it would be helpful to be able to differentiate between insecticides and fungicides, for example. Similarly, what constitutes a regulation would be helpful in terms of knowing if a chemical had been licensed for experimental use only, or if there were any exemptions to its restricted use.

The Office of Toxic Substances (OTS), was created in order to implement TSCA. There is presently no formal mechanism for answering inquiries other than on an *ad hoc* basis, however, there is an Office of Industry Assistance within OTS which responds to general inquiries and directs specific technical questions to appropriate staff.

Within OTS, a *Summary Tabulation of Selected EPA Activities Concerning Toxic Chemicals* was developed primarily for in-house use to assist the staff in knowing the appropriate office to call for information on the status of a particular chemical. Personnel responsible for the document suggested that any new effort respond to those requirements and also, that the focus be shifted from *toxic* substance regulation to *chemical substance* regulation. This document filled three needs:

- awareness of the status of rulemaking
- ability to search on a chemical-specific basis
- knowledge of a contact office within the agency

The Regulations Group within OTS has the responsibility for implementing Section 6 of TSCA which authorizes the Administrator to regulate hazardous chemical substances and mixtures. This group receives a chemical assessment package (assessments of sources, health and environmental effects, level of exposure and an outline of the regulatory alternatives) from either the Special Actions Group or the Hazards Assessment Group, conducts an economic analysis, and develops the regulations. The Regulations Group must also coordinate with other agencies on rulemaking activity, as stipulated in Sections 9(a) and 9(b) of TSCA. It is incumbent upon them to maintain a current awareness of the legal and regulatory jurisdiction of other Federal agencies in order that they might minimize duplication of effort.

The International Activities Office of EPA indicated that the OECD, which has 24 member countries (primarily in Europe), is beginning to direct its attention to the registration and limited use policies of its members pertaining to chemical substances. The OECD Group for Chemicals is a cooperative effort which hopes to serve as the focal point on international regulations and guidelines. It is envisioned as an "information - exchange - consultation" procedure. A Chemical Regulations and Guidelines System would assist in the United States' contribution to the OECD effort as well as could draw from that focal point as a possible source of input.

The Standards and Regulations Office of EPA serves an oversight role in the development of a regulation. They insure that there is a regulation work plan, that attention be given to the methods of compliance, and similar considerations. Since regulation development typically requires six months to two years, it was felt that timeliness could be achieved with a hard copy publication as opposed to an on-line system to maintain a current awareness. A problem might develop if large numbers of regulations were involved. In order to monitor internal EPA regulatory activity for both Headquarters and the Regional Offices, the Standards and Regulations Office irregularly issues a publication known as the "Regulation Development Calendar." It tracks all the actions which are required before a regulation can be promulgated. One of the earliest stages of the regulatory process in EPA is the issuance of a Decision/Action Memo which is approved by the Administrator and then immediately published in the Federal Register (FR) as an Advanced Notice of Proposed Rulemaking. Following this step, a development plan is outlined and the proposed regulation is written. At each stage, a Steering Committee reviews the progress, and prior to publication in the FR, the Assistant Administrators "sign off" on the rule via the "red border" distribution mechanism. An outline of the procedure appears in Figure 2-2. (p.33)

Recommendations were made to identify the responsible office within an agency for a particular regulation, and to include an abstract detailing the specific requirements for compliance. It was also considered important that the IRLG agencies have a means of identifying potentially conflicting and cooperative areas.

Personnel in the EPA Library were contacted to determine how questions on regulations are handled. Inquiries on a specific chemical substance are either forwarded to OPP or to OTS; on the other hand, if the client has the Federal Register or the U.S. Code citation, the librarians provide the text of the designated law as well as some background material which is available from other reference and reporting tools.

2.2.2 Food and Drug Administration (FDA)

Under the Federal Food, Drug, and Cosmetic Act, originally passed in 1906, the Food and Drug Administration was given the authority to protect the public health against impure and unsafe foods, drugs, and cosmetics, and other potential hazards. Initially, the concern was only for the adulteration or mislabeling of these products, however, later amendments to the Act (1938, 1962) took into consideration the efficacy for prescribed use and safety.

FDA is divided into several functional bureaus:

1) Bureau of Biologics (vaccines, e.g.) regulates those products by testing products submitted for registration; approving manufacturers' licenses; evaluating claims for investigational new drugs that are biological products; regulating products shipped in interstate and foreign commerce; and establishing written standards.

2) Bureau of Drugs is concerned with the safety, effectiveness and labeling of drugs for human use. This includes the development of standards for the safety and effectiveness of over-the-counter drugs, the development of guidelines for good manufacturing practices of drugs, and the conduct of research and development of scientific standards in the composition, quality, safety, and efficacy of human drugs.

3) Bureau of Foods monitors and regulates those substances which are food preservatives, food additives, color additives, and cosmetics. This includes activities such as conducting research and developing standards on composition, quality, nutrition, and safety; coordinating and evaluating surveillance and compliance programs; and collecting and analyzing data on nutrition, food additives, and the environmental factors affected by food additives.

4) Bureau of Radiological Health is responsible for the various aspects of radiation exposure.

5) Bureau of Veterinary Medicine controls the safety and efficacy of veterinary preparation and devices.

6) Bureau of Medical Devices and Diagnostic Products is concerned with the safety, efficacy, and labeling of medical devices; developing standards as such; conducting surveillance and monitoring programs; and evaluating premarket approval applications as well as exemption requests for investigational devices.

Incoming inquiries regarding a chemical substance must first be clarified as to how the substance is used before it can be directed to the appropriate bureau for response. Within FDA itself, then, there may be chemical substances which fall into more than one bureau's jurisdiction.

Discussions revealed that promulgating a regulation is not always an option with respect to certain substances. For example, the Cosmetic Law expressly prohibits the regulation of coal-tar hair dyes. In order to effect some kind of restriction, warning labels may be required, and these are published in the Federal Register.

FDA staff cited several specific needs which would facilitate their response capability to outside inquiries and also would assist in their day-to-day administration. The capability of searching on a particular chemical coordinated with its functional use would be extremely valuable. Due to the jurisdictional divisions within FDA, regulations applying to a chemical substance employed as a food additive may not be of the same interest as the identical chemical used as a food preservative. Distinction must be made among active ingredients, inactive ingredients, formulations, generic products, and trade name products. A current awareness or alerting mechanism was mentioned as an important element, as well as the capability of knowing the status of rulemaking.

Status refers to whether a rule is under consideration, has been proposed, or is in effect. The current awareness capability refers to who is doing what, i.e., what agencies have, or are planning, regulations on polyvinyl chlorides, for example. It was recommended that there be some indication of a point of contact within the promulgating agency where further clarification or explanation could be sought. Lastly, since FDA may issue regulations on product or trade names, the inclusion of this as a searchable element must be taken into account.

FDA also emphasized the use of the Universal Product Code (UPC) and/or the National Drug Code (NDC). These are compatible, non-duplicative numbers of ten digits which uniquely identify the manufacturers and their products. The UPC is primarily used with food products and medical devices, whereas the NDC is assigned to drugs. FDA assigns the NDC which is composed of three parts: the labeler code indicating the manufacturer or distributor; the product code; and the package code. All of the health industry is gearing up for use of the NDC and inclusion of this code will facilitate interface with other government-controlled files, such as the Poison Control Index [1](which will be using the NDC as much as possible in the future).

Within the Bureau of Drugs, when a need is realized for a significant regulation (and criteria for that condition are carefully specified), a strategy document is submitted to the Commissioner. Once approval is received, a draft document of the regulation is circulated to the General Counsel's office. The actual details of the draft are confidential until the Commissioner signs the proposed rule, however, general information about the forthcoming regulation is not. The two "early warning" mechanisms used by the Bureau of Drugs are the Advanced Notice of Proposed Rulemaking and the annual plans for regulatory activity which are typically submitted to the Commissioner one year in advance.

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[1] The Poison Control On-line Inquiry System (FDA) gives immediate response to questions concerning the accidental ingestion of approximately 10,000 household products and medicines.

The Bureau of Foods proceeds in a slightly different manner, depending upon which section of the Food, Drug, and Cosmetic Act is being applied. In the case of submission of a petition for labeling requirements, for example, it is reviewed for its environmental and economic impact, and its potential toxicological effects. A notice of receipt of a petition is published in the FR. Once a review is completed, it is published in its final form without any formal public input and it takes effect in thirty days. In instances involving more controversial issues, a strategy document is formulated which presents the pros and cons of an issue with alternative solutions. This is sent to the Commissioner for review and is solely an internal document. Advanced Notice of Rulemaking is rarely used by the Bureau of Foods, however, they do maintain an internal tracking system which monitors and assigns sequential numbers to incoming petitions.

The Office of Regulatory Affairs has the responsibility for issuing a quarterly agenda which lists upcoming actions within FDA. An annual regulations plan for each of the Bureaus was also recently begun. Both of these documents are published in the Federal Register and serve as "previews" to FDA activity.

2.2.3 Consumer Product Safety Commission (CPSC)

The Consumer Product Safety Act (1972) created the CPSC with the authority to establish mandatory safety standards and to ban products from the market. The primary intent was to reduce the risk of injury associated with the use of consumer products. Consumer product safety standards fall into two categories: 1) requirements with respect to performance, composition, contents, design, construction, finish or packaging; 2) requirements relating to clear and adequate warnings or instructions.

The CPSC may develop standards in essentially one of three ways: 1) it may propose a standard for adoption which has already been issued by a qualified public or private agency; 2) it may receive petitions from a person or an organization, such as a trade association or a public interest group, to develop a standard; or 3) it may develop a standard independently under particular circumstances.

Regardless of which of these steps initiates a review, the CPSC staff prepares a position paper on the different aspects of the chemical substance under consideration. This includes health effects and economic impact, for example, all of which are combined into a Briefing Package to be reviewed by the Commissioners. The Commissioners, upon reacting favorably, issue a Notice of Proposed Rulemaking which essentially invites comments from the public, as well as sets the stage for public hearings. It is CPSC's general policy to disclose all information (under the Freedom of Information Act) in the process of regulation development. CPSC has an internal, monthly document called the "Regulatory Development Worklist" which reports the status of projects or actions. In addition, there is a priority listing of CPSC activities which is published. Both of these serve to monitor the areas where CPSC is focusing its attention.

In preparation of the position papers, CPSC would find it extremely valuable to access the regulations and standards on a specific chemical substance developed by the other agencies.

CPSC primarily impacts industry and consumers. It is also heavily dependent on those agencies, particularly OSHA and NIOSH, for the kinds of health and safety determinations which are made in a more defined environment. Criteria Documents and the Standards Completion Program were mentioned as two important sources to include. Consideration of the "alerting" mechanisms of NIOSH and NCI was also encouraged, if only it were to be a minimum reference to their respective research reports.

One office, CPSC's Health Sciences Unit, has been collecting items from the Federal Register on a chemical-specific and individual agency basis for internal use. Future development of an automated system had been anticipated, but was never implemented due to lack of staff. Currently, inquiries coming into CPSC are handled by individual specialists. Therefore, a demonstrable need for a CRGS has already been identified by CPSC staff.

2.2.4 Occupational Safety and Health Administration - OSHA

The passage of the Occupational Safety and Health Act (1970) marked the recognition of the potential health and safety hazards involved in the working environment. Mandatory occupational safety and health standards were to be established and applied to businesses engaging in interstate commerce.

The Act (Public Law 91-596) specifically mentioned toxic substances and authorized the Secretary of Labor to establish standards such that "no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard..." Standards specifically refer to the "conditions, or the ... practices, means, methods, operations or processes, reasonably necessary to provide safe or healthful employment and places of employment" (Section 3.a.1). OSHA must also consider those standards adopted by consensus by a "nationally recognized standard - producing organization," and Federal standards already established. Threshold levels or levels of exposure are used to support regulations pertaining to protective equipment, surveillance and recordkeeping.

In OSHA the regulatory process is initiated by an internal decision to examine the health and safety hazards associated with a particular substance. This formal decision can be triggered by a NIOSH Criteria Document, a petition from a public interest research group, or simply a general awareness of current research activities. A project officer is appointed who is then responsible for making a complete assessment, including site visits and a review of the literature. If it is determined that a standard is required, a draft is developed which encompasses exposure levels, monitoring and recordkeeping requirements, and similar considerations. In the course of developing the standard, an Advanced Notice of Proposed Rulemaking is published in the Federal Register, however, the draft itself remains confidential. Once the draft standard is completed, a Notice of Proposed Rulemaking appears in the FR, followed by public comments and meetings, and then the legally-binding regulation.

OSHA does not conduct its own research activities and is therefore dependent on other agencies, particularly the National Institute for Occupational Safety and Health (NIOSH). NIOSH is specifically charged with the "development of criteria for new and improved occupational safety and health standards" and to "make recommendations concerning new or improved... standards" (PL 91-956, Sec. 22(d)). OSHA relies on NIOSH for the necessary research effort to support the promulgation of standards.

The NIOSH Criteria Documents and the information from the Standards Completion Program were thus recommended for inclusion in a CRGS. Similarly, the evidence gathered by other agencies which result in the development of regulations also impact on OSHA. OSHA staff members indicated a strong desire to know those chemical substances which were under investigation, for example, as possible carcinogens. Awareness of what was about to happen was considered essential to respond to questions accurately and meaningfully. In this way, the most recent developments could be accessed without OSHA staff being dependent on an informal or intermittent notification process.

If an automated system were developed, OSHA recommended a "purge" mechanism for proposed regulations which would be activated only after the final regulation had actually been published. Inclusion of dates for closing comments and the date of effect of a regulation was also urged. Finally, a means of keeping a record of the actual use of CRGS would serve to justify its expense.

Two documents are currently used by the OSHA staff to keep informed of regulatory activity. OSHA circulates periodically an internal document under the title "Health Standards Activity Report." It lists the chemicals under review, the date a criteria document was received, and the dates of publication of advanced notice or proposed rulemaking, publication of proposal, end of comment period, etc. A similar tool encompassing the rulemaking activity of the IRLG agencies would prove extremely useful.

The IRLG Regulatory Work Group circulated in September 1977, a draft of 25 chemicals, the hazards they posed and the action, if any, underway by the member agencies of the IRLG. This initial effort was indicative of a felt need for a chemical regulations and guidelines system.

2.2.5 Other Government Agencies

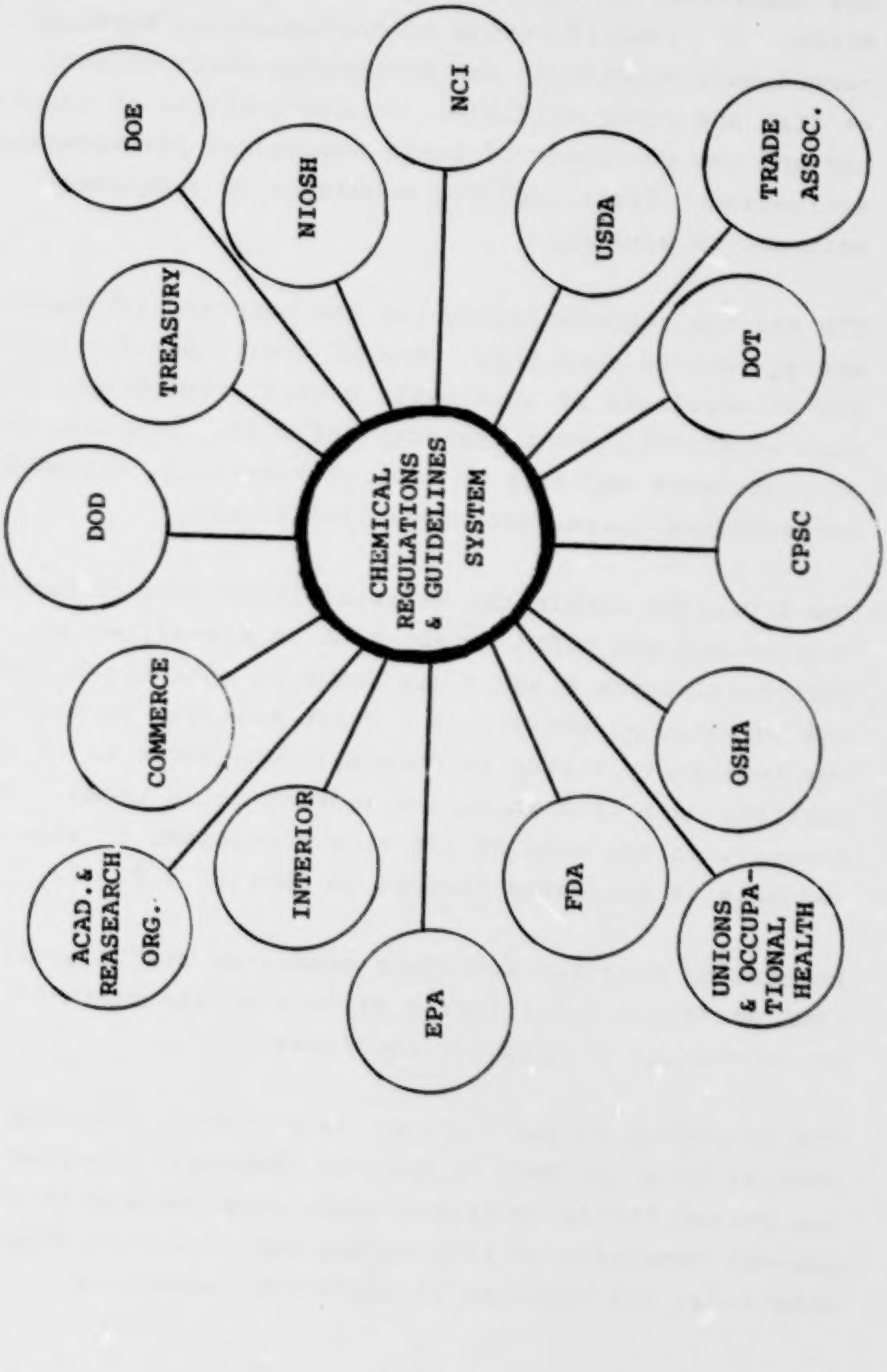
The Mitre Report, Volume II, presented the results of interviews with other government departments and delineated their respective roles in TSCA and how TSCA would impact upon them. It specifically sought to identify the information needs of each agency. Figure 2-1 illustrates the the potential user community for a CRGS, and is based in part, on the Mitre Report, and on the interviews conducted by Sigma Data.

The Department of Commerce, as a member of the Interagency Testing Committee, must evaluate the potential of government regulation to affect commerce, or more specifically, economic development and technological advancement. Their input centers on determining the economic impact of regulation and is a significant part in determining the risk/benefit of the regulatory options. By knowing the existing laws and evaluating their impact, better assessment can be made of proposed regulations.

In the Department of Defense, the Naval Fleet Occupational Health Office was pinpointed as representative of the Department in terms of information needs and current activities. Exposure levels, safe handling techniques, and disposal procedures for toxic substances are of

FIGURE 2-1

ANTICIPATED USERS OF A CHEMICAL
REGULATIONS AND GUIDELINES SYSTEM


CHEMICAL REGULATIONS & GUIDELINES SYSTEM
DOE
NIOSH
NCI
USDA
TRADE ASSOC.
DOT
CPSC
OSHA
UNIONS & OCCUPATIONAL HEALTH
FDA
EPA
INTERIOR
ACAD.& REASEARCH ORG.
COMMERCE
DOD
TREASURY

interest to them. Since these regulatory aspects of toxic substances would be included, CRGS would be responsive to their information needs.

The Department of Interior cited two primary needs to Mitre: 1) identification of carcinogenic, mutagenic and teratogenic substances for monitoring their effects on fish and other wildlife; 2) the location of manufacturers and and the consumers of toxic substances for watershed evaluation. Their need for knowledge of regulatory activity is minimal.

DOE has the responsibility for the hazards assessment of energy-related compounds. One of their specific needs was an awareness of applicable control technology, and this would fall under the scope of CRGS. However, they do place more emphasis on adverse reactions, exposure, environmental data, and production levels.

The divisions within the National Institutes of Health, such as NCI and NIEHS, might also be classified as peripheral users since their focus is entirely on research and educational activities. Their priority is not so much the regulatory status of chemical substances as it is the toxicity data upon which the regulation is based. Their input, however, in the form of alerting mechanisms is significant and this is discussed further in Section 3.2.1.7.

Members of Congress and their committee staffs would find CRGS useful in developing a picture of the state-of-the-art of rulemaking on specific chemicals.

The Secretary of the Treasury is expressly directed by Section 13(a) of TSCA to monitor chemicals imported into the United States to insure their compliance with the law. Current knowledge of regulations pertaining to chemical substances and mixtures is therefore imperative.

The Department of Agriculture has two divisions which are interested in regulations and guidelines pertaining to toxic substances. The Agricultural Research Service, among other activities, works to improve the quality and quantity of crop yield and to protect crops against disease, pests, and pollutants. The Economic Research Service conducts analysis of programs, evaluates the commodity markets, makes projections and analyzes environmental issues. Both of these Services require current awareness of regulations to carry out their work.

The Materials Transportation Bureau within the Department of Transportation is responsible for the transport of hazardous materials in commerce. A "hazardous material" is one which may present an unreasonable risk to health, safety, and property when transported (49 CFR 121.8). The material must be appropriately classified, described, packaged, labeled, and in the required condition for shipment. The Bureau also recommends intermodal and certain modal regulations of hazardous materials. Hazardous materials do include toxic substances and the regulations issued by DOT would be of interest to the other IRLG agencies as well as to industry. Similarly, rulemaking action exercised by the other agencies would be of value to DOT, and might precipitate additional regulations.

2.2.6 Industry

Since rulemaking not only affects, but directs the actions and decisions of industry, it is imperative that they be informed. In fact, CRGS was conceived as a vehicle by which industry would have its inquiries satisfied easily and comprehensively. Industry is particularly interested in proposed rules so that it may respond to notices in the Federal Register.

In addition, court cases, both pending and adjudicated, affect industry. From an economic and legal standpoint, industry's user requirements are most inclusive. In addition to the IRLG agencies, industry is perceived as a primary user.

There are several important trade associations representing chemical manufacturers whose interest lies in regulatory activity including: the Manufacturing Chemists Association (MCA) and the Synthetic Organic Chemical Manufacturers Association (SOCMA). According to the Mitre Report, SOCMA "expresed an interest in a system retrievable by individual chemicals that would provide information concerning relevant standards, labeling, transportation, disposal and packaging requirements." (Vol. II, p. B-86)

SOCMA, whose leadership emphasizes small company problems, indicated further that monitoring of Federal regulations is a time-consuming procedure. A customized awareness tool would prove invaluable to their membership. SOCMA favored the inclusion of recommended standards and practices, but felt a clear distinction should be made between guidelines and regulations. A basic abstract consisting of essential data, such as Time Weighted Averages and Threshold Limit Values was preferred to an extensive summary. It was felt that too much information would encourage the use of the abstract as a substitute for the actual item. Furthermore, a reference to an office within a promulgating agency to explain and interpret regulations would reduce the anonymity of bureaucratic responsibility.

The MCA expressed the usefulness of knowing about Criteria Documents, and other nonregulatory guidelines since they often foreshadow regulation. Individual company guidelines, which are part of Standard Operating Procedures, might also be included, but they are difficult to capture and often are confidential. An abstract would assist in determining if a regulation were relevant and its inclusion in a CRGS was encouraged.

2.2.7 Other Organizations

Unions and other groups concerned with occupational health need to know the required health standards - as well as those which are under consideration - if they are to be responsive to their membership. Three unions that were contacted were the International Association of Heat and Frost Insulators and Asbestos Workers (HFIAW), the International Chemical Workers Union (ICW), and the United Steelworkers of America. Together they represent over 1.5 million members.

The ICW relies on federal and state standards and regulations, the NIOSH "Current Intelligence Bulletins" and Criteria Documents, as well as the documentation which they may glean from other miscellaneous agencies, particularly those in the international and foreign spheres. To a great extent, they also depend upon the Threshold Limit Values (TLVs) developed by the American Conference on Governmental Industrial Hygienists. These TLVs are listed with supporting documentation which the ICW considers extremely useful. Two comments were offered which bear on a Chemical Regulations and Guidelines System. It was important to indicate the responsible office within the agency making the regulation or standard. A brief abstract, either of a descriptive or indicative nature was desirable also. (These remarks were predicated on the ability to search on a chemical-specific basis, and a reference to the citation for the regulation).

The Administrator for Health Hazards of the HFIAW stressed the need for a centralized source to access regulations not only on a chemical-specific basis, but also by trade or product name. Currently he relies upon informal contracts within the government or within other unions and organizations to keep abreast of regulatory activity. Information on state actions, particularly in Oregon, California, and New Jersey, was characterized as "hit or miss." An abstract, written in lay language with the actual method of compliance or the data on exposure levels included, would be considered extremely valuable. It was also recommended that access on a demand basis be established, either via an on-line system, or through a central information service that would have on-line access and would respond to phone inquiries. The inclusion of a contact office within an agency was considered essential since one instance was recalled where fourteen phone calls had been made to one agency in search of further clarification regarding a particular product.

The Department of Safety and Health of the United Steelworkers of America clips the Federal Register on a regular basis, but also subscribes to the reporting services of the Bureau of National Affairs ("Occupational Safety and Health Reporter," and "Chemical Regulation Reporter") and the alerts issued from NIOSH. In formulating a CRGS, it was emphasized that "alerting mechanisms" were of great interest to them since they were anxious to be aware of early warning hazards. The union already maintains liaison people within the different regulatory agencies so there was no expressed need for a "contact" office. In addition, no preference was indicated for an on-line or hard copy version. As long as the original document was accessible, neither was it felt that an abstract be required.

Public Interest Research Groups (PIRGs) such as the Environmental Defense Fund and the Natural Resources Defense Council, often function as watchdog agencies over government action or inaction. Their ability to monitor enforcement of laws and regulations is predicated on their awareness of rulemaking activity. They also may serve a catalysts to rulemaking. While PIRGs are sometimes viewed as a hindrance to government, they may also be effective advocates for the general public.

The National Resources Defense Council, for example, aims to protect the public and the environment against the unreasonable risks presented by chemical substances. They typically identify a potential problem, explore it further to determine its severity and impact, and attempt to inform the public of any hazards. Since their role is dependent upon what information is available to them, they would be interested in more than just the law, but also other relevant standards and guidelines.

The Environmental Defense Fund has established a separate Toxic Chemicals Program to monitor federal activity in that area. Following the inclusion of federal laws and regulations in a CRGS, it was recommended that court cases be covered. Since their primary interest is in litigation, they obviously consider it an important source. NIOSH Criteria Documents and the Standards Completion Program (SCP) are used as prospective and/or reference materials. Again, this reflects their particular stance in a largely advocacy role. The inclusion of state laws was mentioned as extremely significant. The present method of obtaining them is to phone individual state environmental departments, sometimes simply to determine if a law exists.

Heavy reliance is placed on informal mechanisms for procuring information and keeping current. Maintaining personal contacts in the government agencies as well as keeping abreast of medical developments via journals are important sources.

In terms of access, a means of retrieval on a chemical-specific basis with cross-references to synonyms and generic classes was considered a valuable tool. The capability of zeroing in on particular uses of chemicals would be a helpful option, but often it is necessary to know all the ways a chemical is used and/or regulated. Lastly, availability was stated to be vital. They do not have a computer terminal, so at this stage, hard copy would be preferred. However, if the system were to be automated, a public data base would be preferable, presumably because it would cost less.

Other groups who might also find CRGS valuable are academic institutions. They would be particularly interested in chemicals under review as well as regulated chemicals. Also government agencies at the state and local level would likely be users as well, since they do not for the most part, have sufficient resources to devote to standards development.

States are increasingly concerned with environmental health as evidenced by the recent Conference of State Sanitary Engineers which produced a Roster of State Programs with the departmental responsibilities indicated in such areas as occupational health, pesticides, and milk and food protection. (See Bibliography, Appendix D).

2.3 Analysis and Integration of User Requirements

While there are a number of types of users who would be interested in a CRGS, it should be emphasized that the requirements of the system must support the needs of federal agencies on a high priority basis, with the needs of other users receiving secondary consideration.

Following extensive interviewing of the anticipated potential users, Sigma Data combined this information and synthesized the requirements within the framework of the objectives stated in Section 2.1. The user requirements may be divided into four categories:

- Access Capabilities
- Current Awareness
- Informational Content
- Source Material Evaluation

Each of these is explained in greater detail in the following Sections. In turn, these requirements were employed as a basis for the development of a proposed CRGS.

2.3.1 Access Capabilities

The capability of searching on a chemical-specific basis as well as a class of compounds is essential. The questions industry submits are often chemical-specific and smaller companies in particular do not have the resources to monitor federal regulations. To access all the relevant regulations - regardless of the promulgating agency - is an essential requirement as well. Currently neither of these capabilities exist and they would provide the most important and most useful elements of access. The resultant awareness of interagency action on specific chemicals would foster coordination of rulemaking and would facilitate compliance on the part of industry.

Virtually all of the potential users voiced their concern for an access point other than a specific chemical. A means of limiting a query to a use or function of a chemical substance would enhance the retrieval capability far more than the broad jurisdictional responsibility as defined by the promulgating agency. For example, required recordkeeping information about a chemical in a particular environment would be extraneous to requirements pertaining to air transport. A mechanism of this type would also differentiate between regulations and standards, and thus produce more precise output.

On the other hand, it is also sometimes pertinent to access only those regulations of a particular agency, as in the case of a farmer using a pesticide.

Citations to the Federal Register, the U.S. Code, or whatever, should be listed, but there was also a strong indication that an informative abstract would significantly enhance the value of a CRGS.

2.3.2 Current Awareness

Both industry and government personnel indicated that it was not sufficient to know just those regulations that were in effect, but also those that were proposed. In addition, recommended standards were considered significant for inclusion since they were often precursors of actual regulations. While they do not have the force of the law, they nevertheless create a responsibility for liability. The general consensus was that the level of interest was beyond the letter of the law, but extended to what conceivably could become law.

It was further urged by the IEG members that it would be useful to industry to know of regulations which were "in the fire." Figure 2-2 depicts the stages of regulatory development within the four IRLG agencies and how these stages approximately correspond to one another. It is evident that very often Advanced Notices of Proposed Rulemaking serve as early warning mechanisms. For example, in OSHA, this Advanced Notice is issued at the

Figure 2-2

LEVELS IN REGULATION DEVELOPMENT

Level in Development / Agency	EPA	FDA	OSHA	CPSC
Awareness of Potential Hazard	Research /NCI	Alert/NIOSH Bulletin/	Criteria Document/	Petition
Hazard Assessment	Decision/Action Memo	Strategy Document Commissioner Approval	Assignment of Project Officer to review chemical	Commissioner Review Staff Work Review and analysis of health and economic considerations
	ADVANCED NOTICE OF PROPOSED RULEMAKING			
	Development Plan Steering Committee Review		Input of Solicitor's Office	Briefing Package
	DRAFTING OF PROPOSED REGULATION			
Regulation Development	Steering Committee Review "Red Border" Distr.			Commissioner Review
	NOTICE OF PROPOSED RULEMAKING			
	PUBLIC REVIEW AND COMMENT			
	REGULATION RE-DRAFT			
	Steering Committee Rev. "Red Border" Distr. Admin. Signature			
Promulgation of Regulation	FINAL REGULATION			

time that a project officer is reviewing a chemical. CPSC, on the other hand, typically does not issue Advanced Notices; however, it does have a priority list of issues under consideration, and in the past two years, this list has been released annually in the FR.

There are also several other sources which may be tapped for regulation development: in CPSC, the Regulatory Development Work List; in OSHA, the Health Standards Activity Report; and in EPA, the Regulatory Development Calendar. FDA publishes its annual regulations plan and its quarterly agenda in the FR. Thus, there seem to be existing mechanisms for tapping IRLG agency regulatory activity, which is planned or in progress.

Current awareness has another dimension other than the present status of a standard or regulation. It also refers to across-the-board developments, regardless of a particular chemical. Thus, it was considered desirable to be able to review all the standards and regulations which had been promulgated within a recent interval, such as the last month. Instead of waiting to be notified of changes, it would be possible to keep abreast of all the regulations proposed by a certain agency. This would not necessarily require in-depth coverage, but merely provide a scanning or highlight capability.

2.3.3 Informational Content

There was some variation in opinion over the amount of information to be provided with each citation of a standard or regulation. If an abstract were preferred for inclusion, what kind of abstract would it be? How informative?

Or should the actual data of a regulation be succinctly stated in, perhaps , a tabular format? A majority of the users, would be satisfied with the provision of an informative abstract which would, by definition, include the exposure level, or warning label stipulation. The abstract can not be considered as a substitute for the regulation itself, but it would be a concise summary of all the essential elements.

Another aspect of information to be included was the appropriate office within the promulgating agency which could be contacted should there be questions regarding the standard.

2.3.4 Evaluation of Source Material

In determining specifically what subject matter was considered useful for inclusion, three general levels of evaluation criteria were devised. A precise ranking was not considered a valid endeavor since in terms of the law, statute does not carry more force than regulation; and in terms of standards, it is difficult to say that some are more significant or are more worthy than others. Rather than assign numerical values which would be questionably meaningful, it was preferred to assign values of Low, Moderate, and High. Table 2-3 lists the types of sources mentioned for inclusion by potential users who were interviewed. These sources were evaluated against three primary evaluation criteria to determine a measure of their relevance and value to the users.

The three evaluation criteria applied to the input sources were: Functional, Technical, and Economic. Functional considerations are directly derived from the issue of relevance since those source documents most relevant (or functional) are those which have the force of the law.

Source	Functional		Technical		Economic	
	Compliance	Awareness	Availability	Volume	Time (Hrs)	Cost (Dollars)
Federal Regulations - proposed	M	H	H	H	H	L
Federal Regulations - in effect	H	H	H	H	H	L
U.S. Laws	H	H	H	L	L	L
State Laws and Regulations	H	H	H	L	L	H
Court Decisions	H	H	H	M	M	H
Internat'l/Foreign Regulations	M	M	H	L	L	L
Standards Completion Program	L	M	H	M	M	L
Criteria Documents - NIOSH	L	M	H	L	L	L
Bulletins - NIOSH	L	L	H	L	L	L
Chemicals Being Tested (NCI, CBP)	L	L	H	M	L	L

H = High

M = Moderate

L = Low

TABLE 2-3

EVALUATION CRITERIA

What is relevant may be broken down into the two elements of Awareness and Compliance. Awareness refers to the knowledge or cognizance of guidelines, standards, or regulations. In itself it implies no legal accountability. For example, the Standards Completion Program of OSHA and NIOSH does not have any mandate for enforcement, yet it is a recommended federal standard. Compliance, on the other hand, refers to that which is endowed with legal authority, and is therefore binding. Federal regulations would rank high in both Awareness and Compliance (and therefore, Relevance) since there is a need to know that for which there is a responsibility. Documents falling into the Awareness category were cited for mention because, in some cases, they may serve as advance notice of rulemaking which is of great interest to members of the different user groups.

The Technical criteria were divided into Availability and Volume. Availability implies accessibility, that is, how easy or difficult it is to monitor a particular source. Volume refers to the number of standards or regulations which are derived from a specific source. For example, the Federal Register will produce hundreds of regulations, whereas the total number of NIOSH Criteria Documents is less than 80 to date.

Economic criteria were broken down into Time and Cost. Time is measured in terms of person hours anticipated for including and monitoring a source, whereas Cost is the estimated dollar value in subscribing to a publication or service.

Thus, for example, a subscription to the Federal Register would yield Advanced Notice of Proposed Rulemaking, Proposed Regulations and Regulations in effect, as well as a mention of enacted Public Laws.

All of them are necessary input sources and all are easily available. The regulations will take a large amount of time to sift through because of their volume and complexity, but the laws will require less time simply because there are fewer of them. Laws and regulations thus rank High in both Functional and Technical criteria. On the other hand, Criteria Documents are moderately functional in terms of their Awareness capability since by law, they are only recommendations to OSHA to specifically establish regulatory standards. They are easily available, number less than 80, and would not require great investment of time or money. Bulletins issued by NIOSH and NCI, however, were rated Low in terms of their Compliance value, since legally, they are not at all enforceable. Similarly, their Awareness value is also Low since they essentially represent preliminary test results.

2.3.5 Operational Requirements

Based on the user data requirements specified above, Sigma Data deduced certain general operational or systems requirements which must be considered. First, since chemical name and use/application codes have been designated as significant access points, an indexing scheme with extensive cross-references would be required. Secondly, while regulation development is a time-consuming process, often requiring up to a year before promulgation, the number of regulated chemicals is expected to soar (see Section 2.1). Also, the IEG has urged the inclusion of intra-agency activities leading to regulation. These two points argue for a large quantity of information which will demand systematic organization to optimize retrieval. Timeliness or current awareness is thus important, demanding an update mechanism of reasonable frequency, either biweekly or monthly.

Thirdly, the response time for an inquiry to an agency varied considerably, ranging from 2-3 days to a week. The nature and depth of inquiries certainly determine the time needed for formulating a complete response, however, there was never any indication that an immediate response was necessary. Nonetheless, as the number of regulations increase and the subsequent number of inquiries grow, an efficient means will be needed to simply maintain the same turnaround time. Fourthly, since it has been specified that certain kinds of data be included (e.g., CAS Registry Number, abstract, contact office within the promulgating agency, and a citation to the full text of the original document), an ample data storage facility must be developed whose size does not impede retrieval.

On the basis of these operational requirements, Sigma Data considered some kind of automated system to be most useful and appropriate. Possible automation capabilities are discussed in Section 3.1.

3.0 PROPOSED SYSTEM

3.1 System Information Flow

A proposed system purports to incorporate as many as possible of the recommended and desirable features as expressed by the user community. In evaluating the user requirements, Sigma Data considered automation to be the most effective means of implementation. However, automation is not a singular concept, and with respect to the requirements of a CRGS, three possibilities are available:

- Batch Input/Batch Output
- Batch Input/On-line Retrieval
- Batch Input/Hard Copy Publication/(Batch Output)

Table 3-1 presents the advantages and disadvantages of these three alternatives. The most important advantage to batch input and output is its low cost, both in terms of software development and searching. The primary drawback is the lack of a "browsing" capability or a real-time feedback loop to assure the user that the results of the search do, in fact, satisfy the expressed information need. This is, of course, the greatest advantage in an on-line retrieval system where the user is well aware of the output of the search. At any point during the search, the user can modify the query if the search is not producing meaningful results. The hard copy publication alternative eliminates the need for a terminal and a communications network, and keeps software costs to a minimum. However, the disadvantages are numerous. Reprinting volumes and supplying regular supplements may cut into the cost savings of software and communications. Also, the current awareness capability is substantially diminished and is dependent upon the frequency of an update publication. On the other hand, if the update publication were timed with updates to the system file, the current awareness function would not be compromised.

ADVANTAGES AND DISADVANTAGES OF THREE KINDS OF AUTOMATED SYSTEMS

TABLE 3-1

	Advantages	Disadvantages
Batch Input/ Batch Output	o Inexpensive o Response time of no more than 24 hours o No need for extensive communications network	o Requires careful query formulation - no interaction with the system o No immediate response response capability o Requires an information specialist
Batch Input/ On-Line Retrieval	o Interactive capability o Immediate Response o Direct user access to information	o Expensive o Requires terminal, communications network o Requires user training and support
Batch Input/Hard Copy Publication*	o Inexpensive o No need for terminal or communications network	*o Highly structured output o Requires large, manual index o Current awareness element diminished o Reprinting with update o Difficulty in following up on proposed regulations

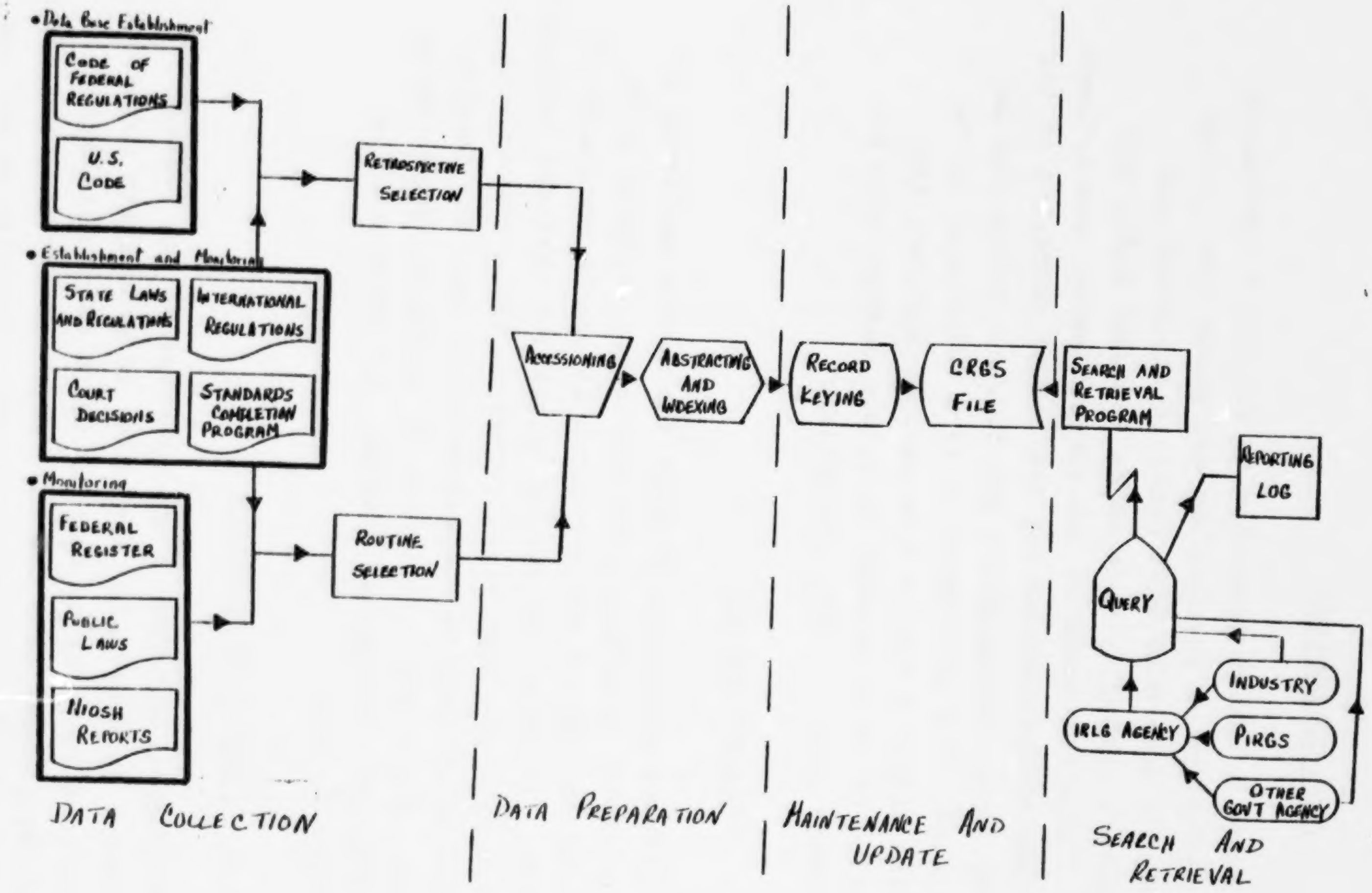
*Batch Output - ad hoc query capability satisfied

Of further concern would be the distribution, involving the development of a mailing list which would present another cost factor. Providing for a batch output in conjunction with a hard copy publication would satisfy the need for ad hoc query. However, in addition to the disadvantages mentioned in the first alternative, there would also be further software and communications costs.

In constructing a model for a general design, Sigma Data determined that the second alternative, a batch input, on-line, interactive retrieval system would be best suited for the maximal satisfaction of user needs. Although a rapid turn around time was not vital, the ability to search on multiple access points was deemed to be a primary consideration. In addition, maximum benefit would be derived from providing for direct user access as opposed to the intervention of an information specialist. Lastly, since the updating requirement is an important aspect of a CRGS, it would be confusing to the user to serially search hard copy publications in an effort to determine the status of proposed regulations.

Implementation options are discussed in greater detail in Section 5.0. Figure 3-2 presents an overall system information flow which is comprised of the following functional components:

- Data Collection
- Data Preparation
- Maintenance and Update
- Search and Retrieval


Data Base Establishment
Code of Federal Regulations
U.S. Code
Establishment and Monitoring
State Laws and Regulations
International Regulations
Court Decisions
Standards Completion Program
Monitoring
Federal Register
Public Laws
NIOSH Reports
Retrospective Selection
Routine Selection
Accessioning
Abstracting and Indexing
Record Keying
CRGS File
Search and Retrieval Program
Reporting Log
Query
IRLG Agency
Industry
PIRGS
Other Gov't Agency
Data Collection
Data Preparation
Maintenance and Update
Search and Retrieval

CHEMICAL REGULATIONS AND GUIDELINES SYSTEM

FLOW DIAGRAM

FIGURE 3-2

A detailed analysis of the Chemical Regulations and Guidelines System proposed by Sigma Data follows.

3.2 Data Collection

In designing a system intending to provide a continuing state-of-the-art on regulations and guidelines, it was necessary to determine what kinds of statutory and nonstatutory authority were to be included under that rubric. Once the scope of the subject matter was defined, mechanisms and procedures for the actual gathering of the material, both retrospective and current, could then be established. The retrospective data collection can be completed within a finite time period; however, the monitoring of other sources to remain current will be the primary facet of data collection.

3.2.1 Subject Matter

The following paragraphs discuss the nature and scope of subject matter comprising the regulatory universe which are to be considered for inclusion as source documents in the CRGS. It should be further clarified that the regulatory universe, for the most part, refers to those conventions or codes which require compliance since they are legally binding. There are other kinds of source documents which were cited for inclusion, however, and these will be discussed as well.

3.2.1.1 Federal Regulations

The Executive departments and agencies of the Federal government each have the authority to promulgate rules and regulations in order to fulfill their responsibilities. These regulations have the full force of the law, and often serve to clarify the law as passed by Congress as well as to assist in implementing the statutory law. Prior to coming into effect, these regulations are first published as "Proposed" and comments are invited from the public.

All regulations - both proposed and in effect - must be published in the Federal Register. Once a year, these regulations are codified and published in the Code of Federal Regulations (CFR). The latter represents all the current general and permanent regulations of the various Federal agencies. It is divided into 50 Titles which represent broad topical areas subject to regulatory action. Those Titles directly relevant to CRGS include:

16 - Commercial Practices (CPSC)
21 - Food and Drugs (FDA)
29 - Labor (OSHA)
40 - Protection of the Environment (EPA)
49 - Transportation (DOT)

Other Titles would apply on a limited basis to CRGS, such as Title 46 (Coast Guard) and Title 30 (Mining and Safety Administration).

3.2.1.2 U.S. Statutes

When a law is enacted, it must be immediately available to the public. The first official publication of the statute is in the form known as a "slip law" which is an unbound pamphlet. Each law is published separately and is assigned an identification number based on the number of the Congress in session followed by a sequential number. For example, the 25th law passed by the 96th Congress would be cited as PL 96-25.

To provide a permanent collection of the laws of each session of Congress, Statues at Large is published. It is simply a chronological arrangement of the laws as they have been passed, with no attempt to arrange them according to subject matter or to show the present status of an earlier law that has been amended.

The U.S. Code is a consolidation and codification of the permanent laws arranged according to subject matter. It specifies the current status of the law, as amended, without repeating the language of the amendments except when necessary. New editions are published every six years and cumulative supplements are published at the conclusion of each regular session of Congress.

Regulations and statutes are without doubt the most important source items to be included in the CRGS since they carry the force of the law. The daily Federal Register lists the public bills which have been enacted with the law number and the Statutes at Large citation. The monitoring of regulations and statutes, therefore, is a fairly straightforward operation.

3.2.1.3 State Laws and Regulations

Several of the individual states, such as New York, Connecticut, and New Jersey, also have legislation which has relevance to the CRGS. This is true particularly in the area of pesticides, but there is some legislation pertaining to hazardous substances. A microfiche collection of environmental legislation compiled by the Environment Information Center in 1976, included 1489 documents pertaining to state laws on air and water pollution, solid waste, pesticides and hazardous substances. These state laws and regulations have limited jurisdiction, of course, but their inclusion was mentioned by several people. Furthermore, they have great relevance and applicability to the industrial community.

3.2.1.4 Court Decisions

Judicial decisions may substantially affect the nature and subsequent enforcement of the law. TSCA itself in Sections

20 and 21, stipulates the procedures for citizen's civil action petitions. The courts having jurisdiction are the U.S. Court of Appeals (D.C.), the Circuit Courts and the U.S. District Courts. Cases may also be appealed to the Supreme Court. The reporting of court decisions is most quickly handled by commercial firms (.e.g, Bureau of National Affairs, West Reporter System), while the official version is usually issued approximately three weeks after the decision is handed down.

In the initial stage of development, Federal laws and regulations should be given the highest priority due to their national jurisdiction. Court decisions, which have the same jurisdiction, and state laws, which have limited jurisdiction but wide interest, should be assigned to the second level of priority.

Once these source documents have been collected and processing is underway, the third phase of data collected would focus on government standards and guidelines, and international and foreign regulations.

3.2.1.5 International/Foreign Regulations

The United States is not the only nation which has taken steps to safeguard the environment. Other countries, such as Canada, Switzerland and Scandanavia, and international organizations, such as the World Health Organization (WHO), the Pan American Health Organization (PAHO) and UNIDO (United Nations Industrial Development Organization) to name a few, have legislated and recommended policies which are relevant to the scope of this project. EPA considers this information useful by virtue of its establishing an International Environmental Reports Collection located in the Washington Headquarters Library. This documentation would be valuable to chemical manufacturers due to the rising level of international trade and investment.

Further evidence of the recognized importance of foreign and international regulatory action is the cooperative effort initiated by the Chemicals Group of the Organization of Economic Cooperation and Development (OECD). They have established an information exchange procedure whereby member countries have a formal mechanism by which their activities with respect to toxic chemicals may be shared, and possibly, coordinated. It appears conclusive that the inclusion of international and foreign regulations and guidelines is highly desirable.

3.2.1.6 Government Standards and Guidelines

There is a whole body of material issued from various government agencies which does not presume to have the force of the law, yet it is considered important because of its potential impact on future regulatory activity. To a degree, they foreshadow regulations and in that capacity, may create a liability on the part of the manufacturer.

The Standards Completion Program is a joint effort by NIOSH and OSHA to draft technical standards to include requirements for informing employees of hazards, acceptable kinds of protective equipment, air sampling and analytical procedures, engineering control procedures, medical surveillance and recordkeeping. Four hundred substances have been listed with their respective exposure levels, and seventeen substances have more comprehensive standards given which include medical surveillance and work place requirements.

3.2.1.7 Current Awareness Documents

There are a number of early warning or current awareness reports which are published by two of the research arms of the Department of Health, Education, and Welfare to notify the regulatory agencies and other interested parties of the potential hazards of chemical substances.

The National Cancer Institute's Carcinogensis Bioassay Program (CBP) issues reports on the chemical substances being tested under its auspices. The Reports themselves are fairly technical and are essentially the detailed results of an investigation. In conjunction with the publishing of the Reports, a news release-type document is available which is directed more towards the general public, the heads of federal departments, and regulatory agencies, industry, and the media. These "Technical Background Information," documents are written in lay language. Their issuance will depend upon, in part, to what extent the chemical is used and by whom.

The CBP also generates a computer printout every 6-8 weeks which is available upon request. It is entitled "Chemicals Being Tested for Carcinogenicity" and is divided into six sections: the name of the chemical; the reports currently available; the status of a completed study, that is, whether it is being evaluated or a report is being prepared; investigations which have produced inconclusive results; chemicals which are under investigations (with the animal, species, route of administration, and the CAS Registry Number); and chemicals which are scheduled for testing.

As indicated by Figure 2-3, the CBP communications serve a low functional requirement with respect to the CRGS since the CBP itself is primarily concerned with making determinations of carcinogenicity and has little direct role in rulemaking. Instead the CBP reports are issued to other government agencies where further investigations may eventually lead to rulemaking activity.

The National Institute for Occupational Safety and Health (NIOSH) issues "Current Intelligence Bulletins" on an irregular basis which are intended to briefly report new information received on occupational hazards. This information serves to advise members of other government agencies, labor, industry, academia, and public interest groups of potentially hazardous substances. In addition to reporting epidemiological and laboratory animal studies, standards for industrial hygiene and exposure levels are recommended.

"Special Occupational Hazard Reviews" are also published by NIOSH and are more in-depth than the "Bulletins." They, instead, aim to evaluate from a health perspective the hazardous effects of a specific chemical and to suggest controls and practices to minimize the problems. They are prepared in such a way as to facilitate the formulation of regulations.

Criteria Documents are published in accordance with Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "develop criteria dealing with the toxic materials and harmful physical agents and substances which will describe ... exposure levels at which no employee will suffer impaired health or functional capabilities or diminished life expectancy as a result of his work experience." These reports, generally the result of 12-18 months preparation time, review the biological effects of exposure, and make specific recommendations for occupational standards including medical surveillance, labeling and posting, protective equipment and clothing, work place air, work practices, sanitation, monitoring and recordkeeping requirements, and informing employees of the hazards. Techniques for sampling and analysis and methods of engineering controls are delineated as well. The Criteria Documents are intended to be a primary justification for regulatory standards.

Knowledge of upcoming regulatory activity was mentioned by several of the users interviewed as important information, even though these kinds of documents or reports have no compliance requirements nor any legal mandate. As was indicated in Table 2-3, these bulletins generally have low functional values. However, since there may be enormous value to be gained from knowing the future directions of regulatory action, these alerting mechanisms were felt by the IEG to be generally within the designated scope of a CRGS, insofar as they pertained to chemical substances or classes of chemicals. They would serve as a guide in the absence of regulation.

The reporting of test results, however, more properly belongs in the Toxicology Data Bank, and in the data base of the Smithsonian Science Information Exchange. There was also some consideration of the intra-agency activity which results in regulation. Figure 2-2 illustrated the comparable actions which precede the promulgation of final regulations. As can be clearly seen, there is early warning of EPA's and OSHA's primary concerns in the form of "Advanced Notice of Proposed Rulemaking" which is published in the Federal Register. The annual priority list released by CPSC, and the annual plan and quarterly agendas issued by FDA also appear in the Federal Register. Thus, the knowledge of regulations under consideration within the IRLG agencies can be monitored through the Federal Register as well as through the internal regulatory calendars used by CPSC, EPA, and OSHA.

However, it must be understood that only the "key stages" of regulatory activity can be reported in CRGS, otherwise there will be no unit record control. These "key stages" are identified in Figure 2-2. However, in order for the IRLG agencies to monitor each step of their internal progress in regulation development, perhaps consideration should be given to developing a subsystem to report the specific steps involved in hazard assessment and regulation development. (Thus, for example, the OSHA Project Officer assigned to a chemical substance would be reported). This capability would foster interagency awareness as well as facilitate the coordination of regulatory action.

3.2.2 Data Base Development

As briefly mentioned, there are three levels of priority for data collection which correspond to three phases of data base development. Since Federal laws and regulations are the first priority for input, they would be processed in the initial stage. Court decisions and state laws and regulations would be collected in the second stage, and government standards and international regulations in the third and final stage of development.

The initial stage of creating a data base also requires that once the sources to be included are identified, a distinction be made between those which demand constant attention, and those which are static. (Certainly the U.S. Code and the CFR are not static in the strictest sense; however, in this context, their respective latest editions are defined as an entity, and therefore are "static." Additions and amendments which relate to them appear first in a separate publication). Other sources, such as the daily Federal Register require regular monitoring.

3.2.2.1 Retrospective Selection

In order to form a comprehensive file of rules and regulations, it is necessary to go back and incorporate those sections and parts of the U.S. Code and Code of Federal Regulations which pertain to chemical substances. This is a one-time operation which would be required in the initial phase of data base development. Since new editions of the U.S. Code are published every six years, it would be necessary to study the cumulative supplements through the last Congress, then the most recent Statutes at Large, and finally the slip laws in order to reach the present. Similarly, the most recent edition of the Code of Federal Regulations would be reviewed.

In order to bring the coverage of federal regulations to date, a monthly publication of the Office of the Federal Register, the List of Sections Affected or LSA (formerly known as the Cumulative List of CFR Sections Affected) must be scanned. Since the relevant Titles have already been identified, the LSA is a useful tool to denote the sections affected and the pages of the Federal Register which apply.

Those sources of standards and regulations which must be examined retrospectively as well as monitored routinely are court decisions, state laws, and international and foreign regulations. There currently exist several services which monitor the courts and the states, and a governmental program which collects the foreign and international documents. Rather than establish a duplicative effort, it would seem more sensible to examine existing information gathering mechanisms and incorporate them into a proposed system.

3.2.2.2 Routine Selection

The source items requiring routine monitoring are the Federal Register, court decisions, (either commercially or by official government publication) and the NIOSH reports. Included in the Federal Register is a list of Public Laws passed with a title of the Act, or a brief description of the Act where a title does not exist. The Public Law number is cited and a copy of the Law may be order from the U.S. Government Printing Office.

3.3 Data Preparation

Once the documents for inclusion have been selected, a standardized procedure must be established for building a unit record for input. Supplying the data elements which comprise the unit record, may be divided into three categories:

- Accessioning
- Abstracting
- Indexing

The document from which a unit record will be constructed will accompany the record through each stage of data preparation. Once the unit record has been completed, the source document itself is dispensable, particularly since reference to the citation appears in the unit record.

3.3.1 Data Elements

The data elements listed below comprise a comprehensive set that are proposed for the CRGS. These data elements will afford the user the maximum degree of flexibility in identifying a chemical substance and the corresponding regulations and guidelines. One of the problems to be resolved in a file such as CRGS is the identification of a chemical substance, product or trade name, and generic names, with the corresponding regulation(s). It would be most appropriate for CRGS to "identify" or code its file records only as stated in the actual regulation, standard, or other source document. This would eliminate any chance of misinterpretation or confusion in the input process, or any errors in retrieval which in itself might cause legal difficulty.

From the user's standpoint, however, it is important to be able to search not only on the product name, for example, but also its ingredients, in order to have a complete and inclusive search on the relevant regulations. Rather than CRGS assume the added responsibility for this, there are a number of existing authority files which can satisfy this requirement, such as the Pesticide Product Information System (EPA), Chemical Formulations of Consumer Products (CPSC), Trade Name Ingredient Classification System (NIOSH), CHEMLINE, and Substructure Search of the CIS (EPA).

CHEMLINE currently provides the capability of searching on chemical names and synonyms, as well as on name fragments which are divided on closures, hyphens, parentheses, commas, and blanks. Until CHEMLINE and/or Substructure Search were integrated into the proposed Chemical Structure/ Nomenclature System[1] of the CSIN, they would be an acceptable tools for chemical substance identification.

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[1] For an extensive description and discussion of the CSNS, see "A Study of System Requirements for Implementing a Chemical Substances Information Network," Sigma Data Computing Corp. Under contract No. EQ7AC003, Amendment #4, October 1977. Section 3.0.

What is recommended for augmenting the identification of chemical in CRGS is the inclusion of the CAS Registry Number. Thus, CRGS would provide access only on the "name" (whether it be chemical name or product name) used in the text of the source document, and on the CAS Registry Number where possible. Product names would, of course, not possess a CAS Number. However, drug products will have a National Drug Code and this, too, is recommended for record augmentation where appropriate.

Arthur Young and Company is presently under contract[1] with the Information Exchange Group of IRLG to develop a plan for implementing a system of codes and preferred names for key data elements used in information systems which are operated by the IRLG agencies. The key data elements that are within the scope of their contract are chemical code and chemical name, product, use and exposure, and business establishment identification. Wherever possible, implementation of a CRGS should consider using these codes and preferred names.

Table 3-3 details the required data elements and a description of each data element follows:

Chemical Names - Chemical substances are identified by a wide variety of naming systems. CRGS will include whichever name is specified in the source document, whether it be a specific chemical name of a generic name.

Product/Trade Names - Identical chemical substances are often marketed by different companies under different brand names. When specified in the source document, these names will be included in the unit record. FDA, for example, often promulgates regulations by product name.

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[1] "Proposal to Develop a Plan for Implementing a System of Common Codes and Preferred Names," under Contract #68-01-4640, May 23, 1978. Arthur Young and Company, Wash., D.C.

CAS/Registry Number - This is a unique nine digit number assigned by chemical substance. The IRLG Information Exchange Workgroup has recommended that this be included as a common interagency identifier wherever possible.

Product Code - Unique ten digit numbers are assigned to food products (Universal Product Code) and drugs (National Drug Code). They are being used increasingly by the health industry as well as the government in information systems. Where appropriate and available, these codes will be included in the unit record.

Source Document Citation - This indicates the reference to the actual regualtion or standard where the full text is printed.

Date of Issue - This refers to the date of issuance or publication of the regulation, proposed regulation or standard. Its inclusion permits a time frame to be associated with the document. Only the month and year are necessary.

Category Code - This identifies the source document, whether it is an international regulation, or a Federal law, or any one of the sources discussed in Sec. 3.2.1.

Jurisdiction Code - Not all of the items to be included in the system have universal legal authority. This code indicates the scope of authority and consists of the following:

- Federal
- State
- Court Decision
- Foreign County
- International
- Other

Regulation Status Code - Due to the diverse nature of the nature comprising the data base, a means of identifying the status of the regulation is necessary. This code indicates if the regulation is proposed, if the regulation is in effect, or if the regulation or standard is under review.

Date in Effect - If the regulation is proposed, the closing date for comments is indicated. Similarly, if the regulation is in effect, the date is given. (This differs from the Date of Issue). Day, month and year must be printed.

Promulgating/Responsible Agency Code - This indicates which agency or organization has developed the standard or regulation.

Contact Office - It is insufficient to mention the agency responsible for a regulation. The contact office within an organization to which questions or further clarification can be directed is necessary.

Phone Number - Similarly to the Contact Office, this indicates, where it is available, the telephone number to be used for additional inquiries.

Abstract - This is a concise, indicative summary which includes the essential information as delineated in the regulation or standard.

Keywords - A Mini-thesaurus provides the capability of specifically structuring a search to produce only those regulations pertaining to a certain subject, such as packaging, standard sampling, or analysis methods. The mini-thesaurus is described further in Section 3.3.4.

TABLE 3-3

DATA ELEMENTS FOR A CHEMICAL REGULATIONS AND GUIDELINES SYSTEM

DATA ELEMENT	SEARCHABLE	PRINTABLE
Chemical Name	x	x
Product/Trade Name	x	x
CAS Registry Number	x	x
Product Code	x	x
Source Document Citation		x
Date of Issue	x	x
Category Code (for source document)	x	x
Jurisdiction Code	x	
Regulation Status Code	x	x
Date in Effect		x
Promulgating/Responsible Agency	x	x
Contact Office		x
Phone Number		x
Abstract	x	x
Keywords	x	x

3.3.2 Accessioning

Accessioning refers to the initial receiving of the document for processing into the system. A data collection form which provides for all the data elements listed in Table 3-3 is attached to each incoming document. The document (which represents a regulation or guideline) is paraphased or encoded into the designated format as outlined by the first thirteen data element in Table 3-3. Where there is no value for a data element (e.g., a standard does not have an effective date), it should be possible to leave the space blank.

3.3.3 Abstracting

The document is then abstracted in an informative style meaning that the essence or substance of the regulation is incorporated into the abstract. The abstract should answer the question: what is the regulation? as opposed to: what is the regulation about?

The recommended average length of the abstract is 300 words which allows sufficient margin for digesting the necessary information as well as minimizing the inexpedience of long, extensive abstracts in an on-line system. As indicated earlier, the Source Document Citation will accompany every record if the full text is desired for further elaboration.

3.3.4 Indexing

Given that chemical substances are used in a varied manner, and that the user community is quite diverse, Sigma Data proposes the use of a mini-thesaurus to encode the regulations in a simple manner which would facilitate retrieval. The indexing scheme is not elaborate nor would it require extensive scope notes or cross-references. It was conceived with the single purpose of being able to differentiate between regulations pertaining to Labeling as opposed to Recordkeeping, for example. Or, in another case, to differentiate between acetone regulated as a pesticide and as it is regulated in its transport by rail. This capability would increase the precision ratio in retrieval.

A prototype of the mini-thesaurus is depicted in Table 3-4. It is not intended to be comprehensive, but only indicative of the type of scheme envisioned. Since the mini-thesaurus should be compact to facilitate ease of use, it could be issued as part of the system documentation.

3.4 Search and Retrieval Capabilities

CRGS provides the user with a broad range of search and retrieval capabilities in order to satisfy the different kinds of inquiries, examples of which are:

- What are all the regulations pertaining to vinyl chloride?
- Does NIOSH have any recommended standards for ethylene dibromide?
- What are the regulations for the shipping of benzene by water?
- Does the State of Nevada have any regulations on the use or manufacture of fungicides? If so, what are they?

The searchable data elements appear in Table 3-3.

Table 3-4

Mini-thesaurus for CRGS

- Air Quality
  - Fuel Additives
  - Monitoring-Sampling

- Color Additives

- Cosmetics

- Distribution
  - Sale
  - Transport
    - Air
    - Land
    - Sea
    - Rail

- Drugs
  - Animal
  - Biologics
  - Human
  - Medical Devices

- Enforcement (Compliance)
  - Storage
  - Testing Protocol

- Food Additives
  - Direct
    - Dietary/Nutritional
    - Preservative
  - Flavoring
  - Indirect
    - Coatings
    - Containers
    - Production Aids
    - Sanitizers

- Labeling
  - Transport
  - Warning

- Manufacture
  - Processing
  - Production

- Pesticides
  - Fungicides
  - Insecticides
  - Rodenticides

- Packaging

- Recordkeeping
  - Medical Surveillance
  - Production
  - Reporting

- Registration
  - Licensing
  - Permits
  - Premarket Notification

- Safety
  - Exemption
  - Limitation
  - Occupational Hazard
  - Tolerance Level

- Solid Waste
  - Collection
  - Disposal
  - Treatment

- Water Quality
  - Effluent Standards
  - Monitoring-Sampling

3.4.1 Searching Strategies

Based on the discussion in Section 3.3.1 concerning the problems involved in the identification of a chemical substance, it was deemed appropriate to consider all possible methods of input and output for that data element. Figure 3-5 illustrates the procedures required for accessioning a source document by substance identifier as well as those procedures for searching by substance identifier.

A free-text search capability was regarded as preferable to a search strategy limited to keywords. Free-text search facilities place greater demands on the user with regard to the specification of "terms" and the ultimate "completeness" of the search strategy. However, when combined with a keyword facility, users are in possession of an added capability for searching. Since free-text searches can be very expensive, and since it would not be appropriate to use free-text searching for fixed data fields, it is recommended that the free-text search capability be limited to the abstract field (records).

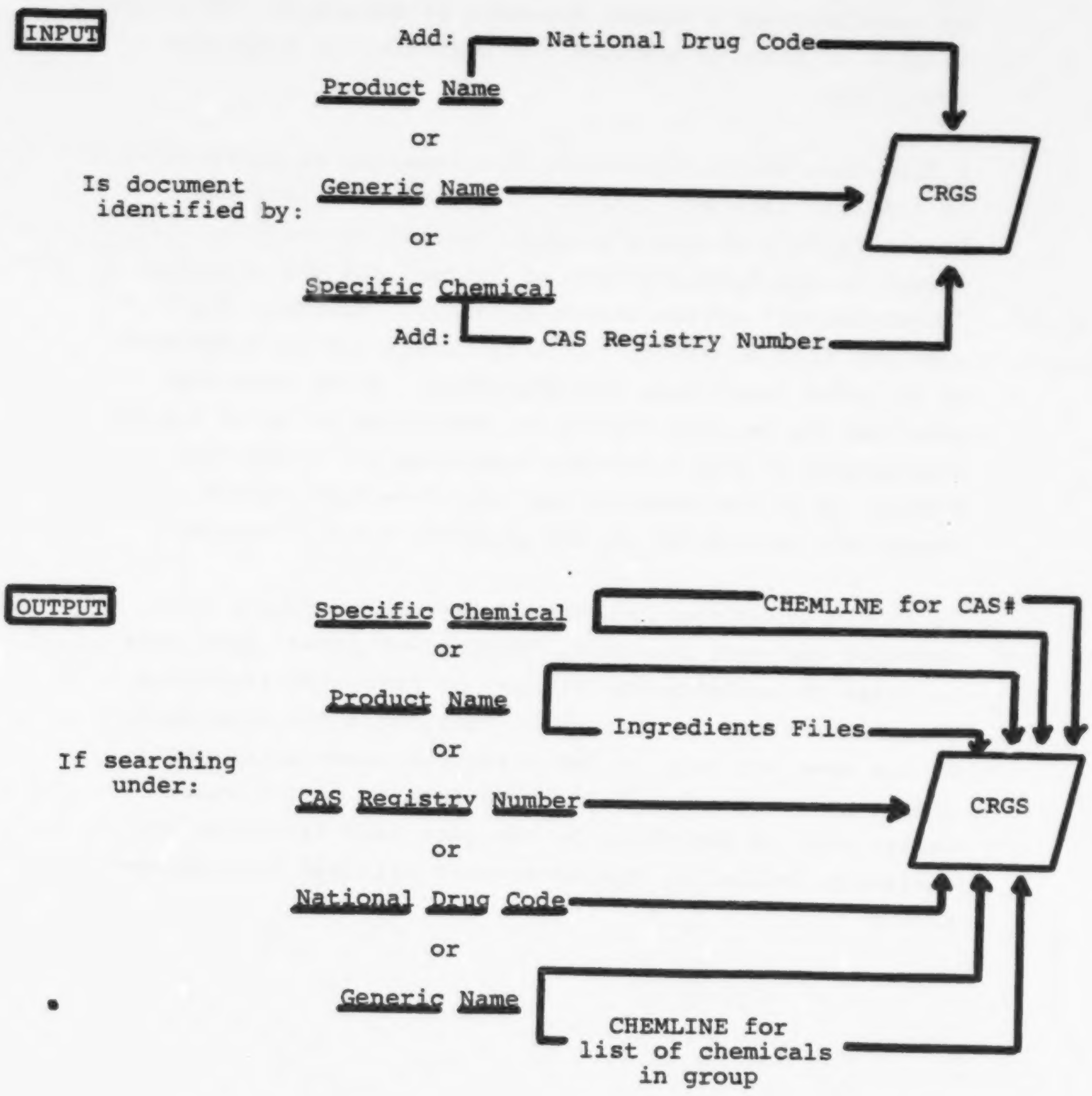
It should be pointed out that free-text searching will increase the need for good, "Keyword-oriented" abstracts in order to maximize the utility of free-text searching. The abstract can be optionally searchable via free-text, or the user may rely on the thesaurus terms which shall appear in a separate field. The details on the exact design will be dependent on the data base structure and operation defined by the contractor selected for implementation.

FIGURE 3-5

INPUT AND OUTPUT PROCESSES

FOR CHEMICAL SUBSTANCE

IDENTIFICATION


INPUT
Add: National Drug Code
Product Name
or
Is document identified by:
Generic Name
or
Specific Chemical
Add: CAS Registry Number
CRGS
OUTPUT
Specific Chemical
CHEMLINE for CAS#
or
Product Name
Ingredients Files
or
If searching under:
CAS Registry Number
or
National Drug Code
or
Generic Name
CHEMLINE for list of chemicals in group
CRGS

The user will also be able to construct a search query by combining any of the data elements listed in Table 3-4 as "searchable." This permits a large degree of flexibility in the retrieval process. Particular versatility is achieved with the mini-thesaurus in order to restrict or expand the scope of the query.

Further clarification should be made between the "Date of Issue" data element and the "Date in Effect" data element since it bears on searching capabilities. Incorporating the date of issue into a unit record is a means of effectuating a common mode of retrieval among all the records comprising the data base. For example, proposed regulations have a date of issue and a date for comment, whereas court decisions have no date other than the one of issue. In order to search for all the rules and regulations issued within a certain period, regardless of their status as proposed or in effect, the date of issue was identified as the common characteristic. Through further searching, it could then be established if the document were a proposed regulation. If it were proposed, the accompanying closing date for comment would also be cited.

3.4.2 Current Awareness

An additional query capability is proposed to facilitate the monitoring of regulations and standards, which may be called SDI, or selective dissemination of information. SDI will permit the storage within the system of a "saved" search, one that has been customized or tailored to the needs of an individual user. For example, instead of a user regularly accessing the data base regarding two or three specific chemicals and their regulation in the United States as well as by the State of Oregon, and each time having to create the same search, the SDI function would invoke the customized profile and would automatically search the file.

3.4.3 User Access

Access to CRGS will be available through on-line, conversational terminal sessions. Due to the potentially diverse nature of the user community, any TTY-compatible terminal will be supported. As indicated in Section 2.2, the user population may consist of Federal government agencies, state government agencies, universities, private industry, unions, and public interest or consumer groups.

Immediate on-line access will provide the greatest utility to the potential user community. Interface with the CSIN will be satisfied at a minimum, by linkages with the Chemical Data Bases Directory (CDBD) and the Chemical Structure Nomenclature System (CSNS). The primary data element linkages will be the CAS Registry Number and the chemical names. While the network configuration, including communications links, of CSIN remains to be determined, there is still a basis for integration via these two data elements. In addition, a subject category vocabulary is under development for the CDBD which will provide another area of linkage (see Section 4.6).

3.5 Data Base Maintenance and Update

Since one of the primary source documents for CRGS is the Federal Register which is issued daily, it will be necessary to support the need for timely information. The frequency of update shall be determined by the contractor responsible for implementation and will be dependent upon the number of items regularly entered into the system. During an update, changes in records will be constructed to reflect those proposed rules which take effect, as well as to accommodate those regulations that had first been published in the Federal Register and codified in the Code of Federal Regulations. In addition, the file must be augmented by new proposed regulations.

In the case of proposed regulations which take effect, a means of purging the file will be created. In some instances, only slight alterations in the original unit record of a proposed regulation are needed. A program, run periodically or in conjunction with an update, could be devised to extract only these items whose date has "passed." The withdrawal of proposed regulations must also appear in the Federal Register. When a proposed regulation is withdrawn, the date of its original issue (or its Federal Register citation) is indicated which provides a means for recalling the original item.

Every time a question is posed to the data base, there would be an automatic recording of that query - not the content of it, but solely the fact that the system was employed to answer a question. This function would be served by a Reporting Log. By the user ID, it would be possible to know which agency was using the system, the volume, and the length of time taken to respond to a specific query. Not only does this facilitate budget analysis, but it furnishes a vehicle for an evaluation of the system through automatic documentation of inquiries.

3.5.1 Data Conversion

All input data will be converted from the data collection form into a machine-readable form. The data collection form will be easily transferable to a keying operation through the use of transaction codes and specified field limits preprinted on the form.

3.5.2 File Organization and Structure

Since a rapid response time to user inquiries will be emphasized in CRGS, the file organization and structure must be able to accommodate the swift search and retrieval of data. Machine-dependent organizational characteristics that increase processing speeds should be employed. Each record of the CRGS data base will contain information for a specific regulation or standard. A structural capability will be furnished to permit retrieval on the searchable data elements specified in Section 3.3.1. In addition, free-text searching will be an option. However, since it is more expensive, consideration should be given to a cost-for-use basis.

It may also be true that a regulation or standard might apply to more than one chemical substance. The file structure should take into account the most cost-effective means of referencing a single abstract by more than one chemical name or CAS number.

A precise examination of the specific user needs for data base retrieval will dictate what type of Data Base Management System (DBMS) is required. DBMS now fall into three general categories: Hierarchical, Network, and Relational. Each type has its advantages and disadvantages; for instance, hierarchical systems are generally best for highly predictable retrieval strategies with few random searching requirements. It is evident, from the above discussion, that a fairly sophisticated DBMS with powerful maintenance facilities will be required to support the CRGS.

4.0 EXISTING CAPABILITIES

4.1 Introduction

Although there is no one source which satisfies all the user requirements, there are several existing systems which bear on one or more of them. It is conceivable that an existing capability might be enhanced to meet the basic requirements; or perhaps selected features of particular systems could be incorporated in the implementation of a CRGS. It is the objective of this section to identify, analyze, and evaluate the applicable existing systems to determine to what extent they are useful.

In the selection of systems to be examined, several considerations were taken into account:

- Data bases or files specified in the Mitre Report as pertinent to regulations and guidelines
- Responsiveness to the question of how to comply versus who complied
- Coverage of one or more of the source items outlined in Section 3.2.1.

An issue to be addressed is the potential conflict between public and private data base development. The question has often been raised concerning the role of the Federal government in an area where it may compete with private enterprise. In the case of a CRGS, there are several commercial firms which market various products that pertain to the input sources discussed in Section 3.2.1. If the Federal government should enter the marketplace as a competitor with a commercial product, there is an obvious and immediate conflict with private enterprise.

If the government were to contract to a private firm for the development of a product, in this case a data base, for which the cost is at least partially financed by the government, would the end costs be so low as to impede other competitors? The question becomes how does the government promote the development of a data base without engaging in any unfair competitive practices. Finally, if a government agency should choose to subscribe to one or more private data bases and to establish a composite file of several sources, there would be a question regarding adherence to the copyright law. Royalty payments are possible but may be somewhat cumbersome to manage justly and effectively.

The sources examined in the following sections were selected on the basis of their relevance to the legal and/or regulatory universe (within the area of chemical substances). Within this broad category, three general subdivisions were identified:

a) Registration/Monitoring/Enforcement Systems
b) Generalized Legal/Regulatory Systems
c) Legal/Regulatory Compliance Systems

4.2 Registration/Monitoring/Enforcement Systems

There are a number of information systems which pertain to the legal and/or regulatory activities of the government but whose primary objectives fall into the specific areas of the registration of products, monitoring of compliance efforts, and enforcement actions. They were developed for internal use by government agencies to assist them in the tracking, surveillance, and monitoring of the expanding use of chemicals in the marketplace. The type of data or information contained in them, however, does not respond to the question of how to comply with laws and regulations, which has been the primary objective of the Chemical Regulations and Guidelines System.

For this reason, these federally supported data bases, both manual and automated, were not considered in the in-depth evaluation of existing systems. However, the systems falling into this category are listed below, and brief descriptions of each appear in Appendix B. It is nonetheless valid however, where appropriate, that common linkages among data bases which are components of the Chemical Substances Information Network (CSIN) be maximized.

Registration

Astro - 4 Drug Information System
Drug Registration and Listing System
Pesticide Product Information System

Monitoring/Enforcement

APTIC - (Air Pollution Technical Information Center)
Compliance Data System
Pesticide Reporting System
Pesticides Enforcement Management System
Technical Data Center

4.3 Generalized Legal/Regulatory Systems

There are several broad-based files which are not specific to the chemical information field, but which encompass a large portion of federal law. Due to their comprehensive scope and/or technical capabilities, they are discussed in brief below.

4.3.1 SCORPIO - Legislative Information File (LIF)

The Library of Congress maintains this file which contains information on public general bills and resolutions.

Routes of access are by bill number, public law number, sponsor, co-sponsor, committee, index terms, actions, and the short title of the bill. The action on bills is monitored and incorporated into the file daily, however, one-and-a-half days generally elapse between action on a bill and when the information is available on LIF. A factual description of the bill is included in the record.

This file is too generalized to make a contribution to a CRGS. Only a small percentage of the law is pertinent to toxic substances. In addition, the focus of a CRGS is not on policymaking but on what is the law. Since notice of public laws appears in the Federal Register, it is not necessary to monitor another source which does not really serve the purpose of a CRGS.

4.3.2 LEXIS

LEXIS is an interactive, automated system maintained by Mead Data which includes in its scope: the U.S. Code, Supreme Court decisions (1938 -); Court of Appeals decisions (1945 -); and cases and/or statutes from twelve states.

Any natural language word may be employed as a search term with multiple terms used with logical connectors. Proximity searching is also available. Documents appear on-line in a full text format since lawyers are very much aware of the inherent weaknesses in abstracts or summaries for legal purposes.

LEXIS is too broad-based for the specific focus of a CRGS. With such a huge file to search, the flexibility of free-text searching would be greatly offset by the time needed to retrieve on a specific chemical name.

In addition, the absence of regulations - a primary component of a CRGS - is a major weakness of LEXIS, and would diminish its usefulness as a base file.

4.3.3 JURIS

JURIS is an on-line, interactive system created and maintained by the U.S. Department of Justice. It is currently used within the Department, in fifty-four U.S. Attorney Offices, and in a few Federal agencies. It is possible for a Federal agency to employ JURIS either by requesting a search or, for regular use, by undergoing a training session and having direct access through the Justice Department. The content of JURIS includes:

- Supreme Court decisions: 1900 - date
- Court of Claims: 1956 - date
- Court of Appeals: 1962 - date
- District Court: 1970 - date
- U.S. Code (1970) and Supplement 2: 1975

The Federal Register and the CFR are expected to be included within the next two years. Case law is updated weekly; statutory law, monthly; and the FR will be updated weekly. All documents appear in the system in a full text format and searching is conducted on a free-text basis or through the subject codes developed by the West Publishing Company.[1] Searching on headnotes (digested court opinions) is also an option.

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[1] There are 414 topical subject headings established by West Publishing Co., the main publisher in the legal field. Examples are: Drugs and Narcotics, Health and Environment, and Products Liability.

The cost of JURIS is $60/hour for connect time. JURIS staff will also conduct searches for selected customers charging $23/hour for their time. Offline print charges are $.006/line with a $5.00 minimum.

JURIS is an extremely comprehensive legal data base whose focus is not limited enough for extensive use in a CRGS. Too much of its material is extraneous and this would not facilitate an effective searching capability. Chemical-specific access would be limited to a free-text capability. While JURIS itself is inappropriate for a CRGS, it might be suitable as a data collection mechanism if the IRLG/IEG preferred to implement a public, government-supported data base. This alternative will be discussed in greater detail in Section 5.5.

4.3.4 Congressional Information Service (CIS)

This commercial firm makes available CIS Index which covers U.S. Congress publications, including hearings; committee prints; House and Senate Reports, Documents and special publications; and Senate Executive Reports and Documents. Public Laws are added only on an annual basis. Since CRGS would be interested in Public Laws only, and not the policymaking comprising them, this file was not considered appropriate.

4.4 Legal/Regulatory Compliance System

There are a number of commercial services which were identified as potential sources for the development of a CRGS. While none of them as they presently exist meet the criteria of the proposed system, several of them manifest certain capabilities which might be further enhanced. Table 4-1 lists these commercial services and the subject matter coverage included in each. The source document coverage is

	Primary				Secondary		
	Regs.	Statutes	Court Decisions	State Laws	Internat'l Regs.	SCP Standards	Total
CSI	1	1	0	0	0	0	2
EIC	1[b]	1	0	1	0	0	3[b]
ELI	1	1	1	0	0	0	3
BNA	1[b]	1	1	0	1	1	5[b]
IHS	1	1	1[c]	1	0	0	4
PREDICASTS	1	0	0	0	0	0	1
SUMMARIES OF INTERNAT'L ENVIR. RPTS.	0	0	0	0	1	0	1
RTECS	0	0	0	0	0	1	1
JURIS	1[a]	1	1	0	0	0	3

[a] planned

[b] does not report on FDA

[c] only U.S. Supreme Court

TABLE 4-1

SUBJECT MATTER COVERAGE IN EXISTING SYSTEMS divided into Primary and Secondary components, based on the Compliance evaluation in Table 2-2. A scheme was devised whereby a point was awarded when a particular source item was monitored by an existing system. The total number of points demonstrate which systems presently have the most coverage. This should not be construed as the sole criterion, because other capabilities such as access points, are equally as important. However, this subject matter determination will filter out those systems which cannot serve as a foundation for development of a CRGS. Those systems scoring two or more points are discussed in detail in the following section, whereas the three systems scoring less than two are discussed in Appendix C.

4.4.1 Capitol Services, Inc.

Capitol Services, Inc. (CSI) is a commercial firm which monitors the Federal Register and the Congressional Record on a daily basis. This monitoring operation is demonstrated by two products: an on-line capability available through Systems Development Corporation's ORBIT, and a daily published summary of each source. Subscriptions to the summary reports are available on a custom profile basis, or on what is known as a "master edition" which abstracts the entire contents of the Federal Register.

Brief abstracts accompany each citation and they are writted with great attention to incorporating keywords. CSI stresses the inclusion of as much information as is available in order to accommodate its subscribers. The kinds of information appearing in each reference are:

- Complete citation to the FR
- References back to original notices and/or proposals
- CAS Registry Number whenever it is cited in the FR itself
- Agency name

- Docket number
- Petition number
- Reference to relevant Title and part of CFR
- Corporate names (primary ones affected)
- Public Law notice (including bill number, Public Law number, Statutes at Large number, and brief intent)
- Effective dates
- Meeting announcements
- Proposed and notice of proposed rulemaking

A sample page, available courtesy of CSI, is shown in Figure 4-2.

In order to provide custom profiles to subscribers, CSI has developed a Subject Checklist of 250 topics. This is reprinted in Figure 4-3, however, the following have been extracted for their immediate relevance to a CRGS:

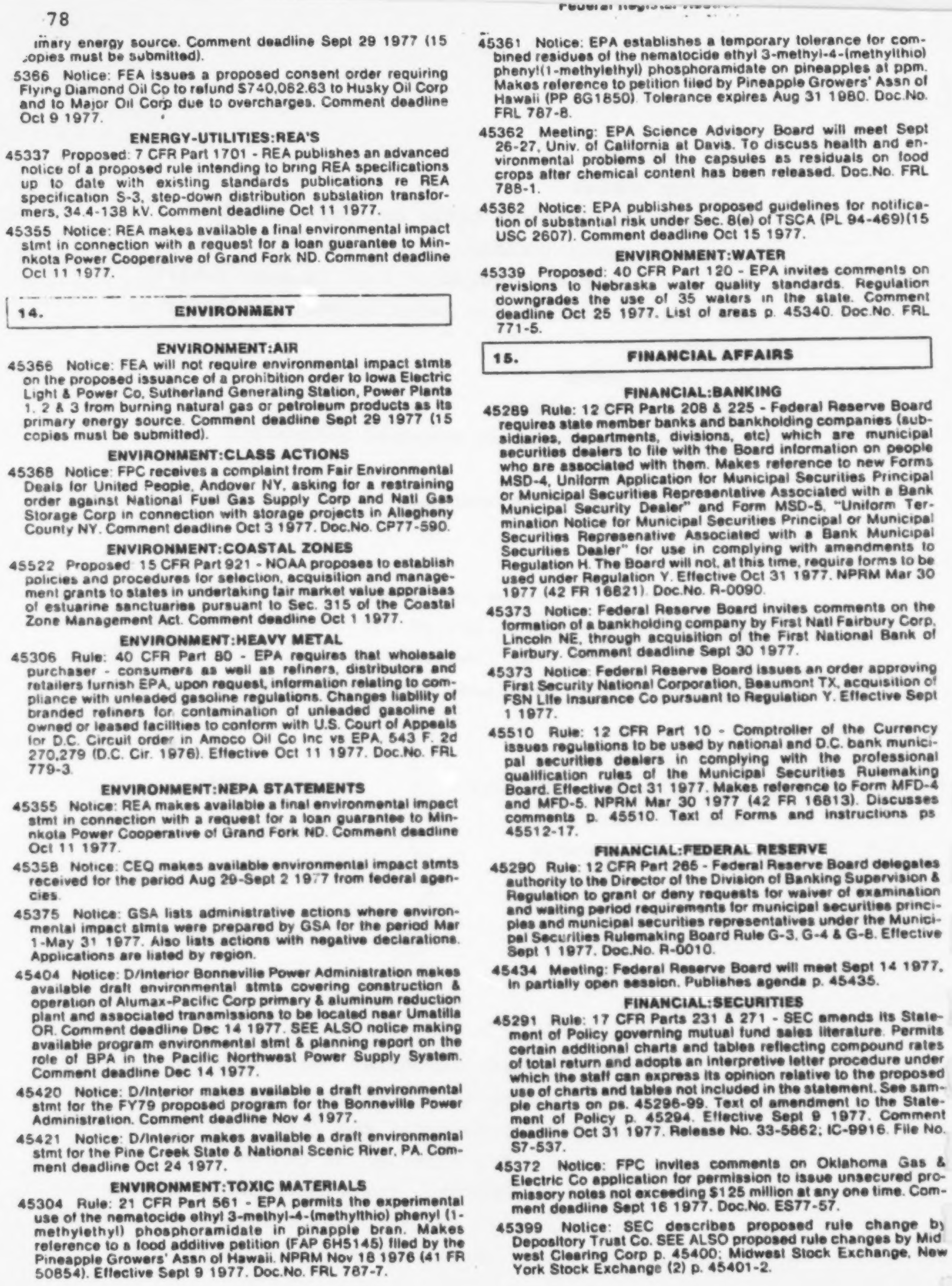
- Food and Drug
- Packaging and Labeling
- Product Safety
- Product Standards

} Consumer

- Toxic Materials
- Air
- Solid Waste
- Water

} Environment

These are obviously broad categories, but since CSI emphasizes keyword abstracts and since free-text searching is available in the on-line mode, the retrieval capabilities are greatly expanded. For example, as can be seen from Figure 4-2, under ENVIRONMENT: TOXIC MATERIALS, the chemical name is used. It is also possible to search on the different subject codes designated by CSI (Figure 4-3).



imary energy source. Comment deadline Sept 29 1977 (15 copies must be submitted).

5366 Notice: FEA issues a proposed consent order requiring Flying Diamond Oil Co to refund $740,062.63 to Husky Oil Corp and to Major Oil Corp due to overcharges. Comment deadline Oct 9 1977.

ENERGY-UTILITIES:REA'S

45337 Proposed: 7 CFR Part 1701 - REA publishes an advanced notice of a proposed rule intending to bring REA specifications up to date with existing standards publications re REA specification S-3, step-down distribution substation transformers, 34.4-138 kV. Comment deadline Oct 11 1977.

45355 Notice: REA makes available a final environmental impact stmt in connection with a request for a loan guarantee to Minnkota Power Cooperative of Grand Fork ND. Comment deadline Oct 11 1977.

14. ENVIRONMENT

ENVIRONMENT:AIR

45366 Notice: FEA will not require environmental impact stmts on the proposed issuance of a prohibition order to Iowa Electric Light & Power Co, Sutherland Generating Station, Power Plants 1, 2 & 3 from burning natural gas or petroleum products as its primary energy source. Comment deadline Sept 29 1977 (15 copies must be submitted).

ENVIRONMENT:CLASS ACTIONS

45368 Notice: FPC receives a complaint from Fair Environmental Deals for United People, Andover NY, asking for a restraining order against National Fuel Gas Supply Corp and Natl Gas Storage Corp in connection with storage projects in Allegheny County NY. Comment deadline Oct 3 1977. Doc.No. CP77-590.

ENVIRONMENT:COASTAL ZONES

45522 Proposed: 15 CFR Part 921 - NOAA proposes to establish policies and procedures for selection, acquisition and management grants to states in undertaking fair market value appraisas of estuarine sanctuaries pursuant to Sec. 315 of the Coastal Zone Management Act. Comment deadline Oct 1 1977.

ENVIRONMENT:HEAVY METAL

45306 Rule: 40 CFR Part 80 - EPA requires that wholesale purchaser - consumers as well as refiners, distributors and retailers furnish EPA, upon request, information relating to compliance with unleaded gasoline regulations. Changes liability of branded refiners for contamination of unleaded gasoline at owned or leased facilities to conform with U.S. Court of Appeals for D.C. Circuit order in Amoco Oil Co Inc vs EPA, 543 F. 2d 270,279 (D.C. Cir. 1976). Effective Oct 11 1977. Doc.No. FRL 779-3.

ENVIRONMENT:NEPA STATEMENTS

45355 Notice: REA makes available a final environmental impact stmt in connection with a request for a loan guarantee to Minnkota Power Cooperative of Grand Fork ND. Comment deadline Oct 11 1977.

45358 Notice: CEQ makes available environmental impact stmts received for the period Aug 29-Sept 2 1977 from federal agencies.

45375 Notice: GSA lists administrative actions where environmental impact stmts were prepared by GSA for the period Mar 1-May 31 1977. Also lists actions with negative declarations. Applications are listed by region.

45404 Notice: D/Interior Bonneville Power Administration makes available draft environmental stmts covering construction & operation of Alumax-Pacific Corp primary & aluminum reduction plant and associated transmissions to be located near Umatilla OR. Comment deadline Dec 14 1977. SEE ALSO notice making available program environmental stmt & planning report on the role of BPA in the Pacific Northwest Power Supply System. Comment deadline Dec 14 1977.

45420 Notice: D/Interior makes available a draft environmental stmt for the FY79 proposed program for the Bonneville Power Administration. Comment deadline Nov 4 1977.

45421 Notice: D/Interior makes available a draft environmental stmt for the Pine Creek State & National Scenic River, PA. Comment deadline Oct 24 1977.

ENVIRONMENT:TOXIC MATERIALS

45304 Rule: 21 CFR Part 561 - EPA permits the experimental use of the nematocide ethyl 3-methyl-4-(methylthio) phenyl (1-methylethyl) phosphoramidate in pinapple bran. Makes reference to a food additive petition (FAP 6H5145) filed by the Pineapple Growers' Assn of Hawaii. NPRM Nov 18 1976 (41 FR 50854). Effective Sept 9 1977. Doc.No. FRL 787-7.

45361 Notice: EPA establishes a temporary tolerance for combined residues of the nematocide ethyl 3-methyl-4-(methylthio) phenyl(1-methylethyl) phosphoramidate on pineapples at ppm. Makes reference to petition filed by Pineapple Growers' Assn of Hawaii (PP 6G1850). Tolerance expires Aug 31 1980. Doc.No. FRL 787-8.

45362 Meeting: EPA Science Advisory Board will meet Sept 26-27, Univ. of California at Davis. To discuss health and environmental problems of the capsules as residuals on food crops after chemical content has been released. Doc.No. FRL 788-1.

45362 Notice: EPA publishes proposed guidelines for notification of substantial risk under Sec. 8(e) of TSCA (PL 94-469)(15 USC 2607). Comment deadline Oct 15 1977.

ENVIRONMENT:WATER

45339 Proposed: 40 CFR Part 120 - EPA invites comments on revisions to Nebraska water quality standards. Regulation downgrades the use of 35 waters in the state. Comment deadline Oct 25 1977. List of areas p. 45340. Doc.No. FRL 771-5.

15. FINANCIAL AFFAIRS

FINANCIAL:BANKING

45289 Rule: 12 CFR Parts 208 & 225 - Federal Reserve Board requires state member banks and bankholding companies (subsidiaries, departments, divisions, etc) which are municipal securities dealers to file with the Board information on people who are associated with them. Makes reference to new Forms MSD-4, Uniform Application for Municipal Securities Principal or Municipal Securities Representative Associated with a Bank Municipal Security Dealer" and Form MSD-5, "Uniform Termination Notice for Municipal Securities Principal or Municipal Securities Represenative Associated with a Bank Municipal Securities Dealer" for use in complying with amendments to Regulation H. The Board will not, at this time, require forms to be used under Regulation Y. Effective Oct 31 1977. NPRM Mar 30 1977 (42 FR 16821). Doc.No. R-0090.

45373 Notice: Federal Reserve Board invites comments on the formation of a bankholding company by First Natl Fairbury Corp, Lincoln NE, through acquisition of the First National Bank of Fairbury. Comment deadline Sept 30 1977.

45373 Notice: Federal Reserve Board issues an order approving First Security National Corporation, Beaumont TX, acquisition of FSN Life Insurance Co pursuant to Regulation Y. Effective Sept 1 1977.

45510 Rule: 12 CFR Part 10 - Comptroller of the Currency issues regulations to be used by national and D.C. bank municipal securities dealers in complying with the professional qualification rules of the Municipal Securities Rulemaking Board. Effective Oct 31 1977. Makes reference to Form MFD-4 and MFD-5. NPRM Mar 30 1977 (42 FR 16813). Discusses comments p. 45510. Text of Forms and instructions ps 45512-17.

FINANCIAL:FEDERAL RESERVE

45290 Rule: 12 CFR Part 265 - Federal Reserve Board delegates authority to the Director of the Division of Banking Supervision & Regulation to grant or deny requests for waiver of examination and waiting period requirements for municipal securities principles and municipal securities representatives under the Municipal Securities Rulemaking Board Rule G-3, G-4 & G-8. Effective Sept 1 1977. Doc.No. R-0010.

45434 Meeting: Federal Reserve Board will meet Sept 14 1977, in partially open session. Publishes agenda p. 45435.

FINANCIAL:SECURITIES

45291 Rule: 17 CFR Parts 231 & 271 - SEC amends its Statement of Policy governing mutual fund sales literature. Permits certain additional charts and tables reflecting compound rates of total return and adopts an interpretive letter procedure under which the staff can express its opinion relative to the proposed use of charts and tables not included in the statement. See sample charts on ps. 45296-99. Text of amendment to the Statement of Policy p. 45294. Effective Sept 9 1977. Comment deadline Oct 31 1977. Release No. 33-5862; IC-9916. File No. S7-537.

45372 Notice: FPC invites comments on Oklahoma Gas & Electric Co application for permission to issue unsecured promissory notes not exceeding $125 million at any one time. Comment deadline Sept 16 1977. Doc.No. ES77-57.

45399 Notice: SEC describes proposed rule change by Depository Trust Co. SEE ALSO proposed rule changes by Midwest Clearing Corp p. 45400; Midwest Stock Exchange, New York Stock Exchange (2) p. 45401-2.

Figure 4-2

CSI Subject Checklist

MARK: ☐ For Congressional Record Selections
○ For Federal Register Selections

AGRICULTURE:
- ☐ ○ General*
- ☐ ○ Agribusiness
- ☐ ○ Animal/Plant Health
- ☐ ○ Commodity Programs
- ☐ ○ Conservation
- ☐ ○ Credit
- ☐ ○ Domestic Marketing
- ☐ ○ Farm Prices
- ☐ ○ Foreign Marketing
- ☐ ○ Inspection/Grading
- ☐ ○ Production
- ☐ ○ Research
- ☐ ○ Rural Development

AMERICANISM:
- ☐ ○ General*
- ☐ ○ Bicentennial
- ☐ ○ Patriotic Statements/Events

ARTS & HUMANITIES:
- ☐ ○ General*
- ☐ ○ Federal Programs
- ☐ ○ Private Programs

ATHLETICS:
- ☐ ○ General*
- ☐ ○ Olympic
- ☐ ○ Professional
- ☐ ○ Scholastic

BUSINESS:
- ☐ ○ General*
- ☐ ○ Antitrust
- ☐ ○ Multinational
- ☐ ○ Records/Reporting
- ☐ ○ Regulatory Reform
- ☐ ○ Small & Minority

CENSUS:
- ☐ ○ (All major references)

COMMUNICATIONS:
- ☐ ○ General*
- ☐ ○ Broadcast
- ☐ ○ CATV
- ☐ ○ Information Systems
- ☐ ○ Print
- ☐ ○ Public Broadcasting
- ☐ ○ Satellite
- ☐ ○ Telecommunications
- ☐ ○ Telephone/Telegraph

CONSTITUTIONAL/HUMAN RIGHTS:
- ☐ ○ General*
- ☐ ○ Abortion
- ☐ ○ Discrimination
- ☐ ○ Privacy
- ☐ ○ Speech & Press
- ☐ ○ Women's Rights

CONSUMER:
- ☐ ○ General*
- ☐ ○ Advertising
- ☐ ○ Advocacy
- ☐ ○ Class Actions
- ☐ ○ Credit
- ☐ ○ Education
- ☐ ○ Food & Drug
- ☐ ○ Packaging & Labeling
- ☐ ○ Product Safety
- ☐ ○ Product Standards
- ☐ ○ Trade Practices
- ☐ ○ Warranties

CONTRACTS:
- ☐ ○ General*
- ☐ ○ Cost Accounting
- ☐ ○ Govt Procurement
- ☐ ○ Provisions
- ☐ ○ Renegotiation
- ☐ ○ Review

COPYRIGHT:
- ☐ ○ (All major references)

DEFENSE:
- ☐ ○ General*
- ☐ ○ Civil Defense
- ☐ ○ Facilities & Construction
- ☐ ○ Personnel & Manpower
- ☐ ○ Procurement
- ☐ ○ Production
- ☐ ○ Research & Development
- ☐ ○ Weapons Systems

DISTRICT OF COLUMBIA:
- ☐ ○ (All major references)

ECONOMY:
- ☐ ○ General*
- ☐ ○ Cost of Living
- ☐ ○ Development Assistance
- ☐ ○ Employment/Unemployment
- ☐ ○ Monetary Policy
- ☐ ○ Productivity
- ☐ ○ Wage & Price Controls

EDUCATION:
- ☐ ○ General*
- ☐ ○ Desegregation
- ☐ ○ Elementary & Secondary
- ☐ ○ Higher
- ☐ ○ Private
- ☐ ○ Special Programs
- ☐ ○ Student Assistance
- ☐ ○ Vocational

ENERGY/UTILITIES:
- ☐ ○ General*
- ☐ ○ Electric
- ☐ ○ Federal Systems
- ☐ ○ Geothermal
- ☐ ○ Natural Gas
- ☐ ○ Nuclear
- ☐ ○ Policy
- ☐ ○ REA's
- ☐ ○ Solar & Exotic

ENVIRONMENT:
- ☐ ○ General*
- ☐ ○ Air
- ☐ ○ Class Actions
- ☐ ○ Coastal Zones
- ☐ ○ Heavy Metal
- ☐ ○ Land Use
- ○ NEPA Statements
- ☐ ○ Noise
- ☐ ○ Population
- ☐ ○ Radiation
- ☐ ○ Solid Waste
- ☐ ○ Toxic Materials
- ☐ ○ Water

FINANCIAL:
- ☐ ○ General*
- ☐ ○ Banking
- ☐ ○ Bankruptcy
- ☐ ○ Commodity Trading
- ☐ ○ Credit Unions
- ☐ ○ Federal Reserve
- ☐ ○ Interest Rates
- ☐ ○ International Institutions
- ☐ ○ S & L's
- ☐ ○ SBIC's
- ☐ ○ Securities

FISCAL AFFAIRS:
- ☐ ○ General*
- ☐ ○ Appropriations
- ☐ ○ Congressional Budget
- ☐ ○ President's Budget

FOREIGN AFFAIRS:
- ☐ ○ General*
- ☐ ○ Agreements
- ☐ ○ Arms Control
- ☐ ○ Country Relations
- ☐ ○ Defense Alliances
- ☐ ○ Economic Aid
- ☐ ○ Intelligence
- ☐ ○ International Organizations
- ☐ ○ Military Aid/Sales
- ☐ ○ Refugee Programs
- ☐ ○ State Dept Administration

HEALTH:
- ☐ ○ General*
- ☐ ○ Alcohol & Drug Abuse
- ☐ ○ Institutional
- ☐ ○ Medicare & Medicaid
- ☐ ○ Mental
- ☐ ○ Natl Insurance Programs
- ☐ ○ Research
- ☐ ○ Services
- ☐ ○ Training

HOUSING:
- ☐ ○ General*
- ☐ ○ Community Development
- ☐ ○ Discrimination
- ☐ ○ Financing
- ☐ ○ Standards

IMMIGRATION:
- ☐ ○ (All major references)

INDIAN AFFAIRS:
- ☐ ○ (All major references)

INSURANCE:
- ☐ ○ General*
- ☐ ○ Federal Programs
- ○ Flood Insurance
- ☐ ○ Regulation

LABOR:
- ☐ ○ General*
- ☐ ○ Agriculture
- ☐ ○ Equal Employment
- ☐ ○ Manpower Training
- ☐ ○ Private Pension Plans
- ☐ ○ Public Employees
- ☐ ○ Railroad
- ☐ ○ Safety & Health
- ☐ ○ Strikes & Boycotts
- ☐ ○ Unemployment & Workmens Comp
- ☐ ○ Wages & Hours

LAW ENFORCEMENT:
- ☐ ○ General*
- ☐ ○ Administration
- ☐ ○ Assistance
- ☐ ○ Civil Actions
- ☐ ○ Firearms Control
- ☐ ○ Institutions
- ☐ ○ Internal Security
- ☐ ○ Judiciary
- ☐ ○ Legal Profession

PARKS & RECREATION:
- ☐ ○ General*
- ☐ ○ Historic Sites
- ☐ ○ Indoor Facilities
- ☐ ○ Natl Parks & Recreation Areas
- ☐ ○ Scenic Rivers & Trails
- ☐ ○ Wilderness

PATENTS:
- ☐ ○ (All major references)

POLITICAL:
- ☐ ○ General*
- ☐ ○ Advertising/Equal Time
- ☐ ○ Disclosure
- ☐ ○ Elections
- ☐ ○ Ethics
- ☐ ○ Executive Relations
- ☐ ○ Hatch Act
- ☐ ○ Legislative
- ☐ ○ Lobbying
- ☐ ○ Party Reform

POSTAL:
- ☐ ○ General*
- ☐ ○ Personnel
- ☐ ○ Rates
- ☐ ○ Regulations
- ☐ ○ Service

RELIGIOUS AFFAIRS:
- ☐ ○ (All major references)

RESOURCES:
- ☐ ○ General*
- ☐ ○ Forests
- ☐ ○ Minerals
- ☐ ○ Oceanographic
- ☐ ○ Oil & Gas
- ☐ ○ Outer Shelf
- ☐ ○ Public Lands
- ☐ ○ Public Works
- ☐ ○ Strategic Materials
- ☐ ○ Wildlife & Fisheries

SOCIAL SERVICES:
- ☐ ○ General*
- ☐ ○ Aging
- ☐ ○ Anti-Poverty
- ☐ ○ Child & Family Services
- ☐ ○ Day Care
- ☐ ○ Food & Nutrition
- ☐ ○ Handicapped
- ☐ ○ Legal Services
- ☐ ○ Non-English Speaking
- ☐ ○ SSI
- ☐ ○ Social Security

STATE/LOCAL RELATIONS:
- ☐ ○ General*
- ☐ ○ Revenue Sharing

TAXES:
- ☐ ○ General*
- ☐ ○ Ad Valorem
- ☐ ○ Capital Gain
- ☐ ○ Corporate Rates/Policy
- ☐ ○ Depreciation
- ☐ ○ Estate
- ☐ ○ Excises
- ☐ ○ Exempt Organizations
- ☐ ○ Export Incentives
- ☐ ○ Foreign Income
- ☐ ○ Investment Credit
- ☐ ○ Minimum Tax
- ☐ ○ Municipal Bonds
- ☐ ○ Personal
- ☐ ○ Pollution
- ☐ ○ Resource

TECHNOLOGY:
- ☐ ○ General*
- ☐ ○ Aerospace
- ☐ ○ Assessment
- ☐ ○ Atomic Energy
- ☐ ○ Fire Prevention
- ☐ ○ Standards
- ☐ ○ Weather

TERRITORIES:
- ☐ ○ (All major references)

TRADE:
- ☐ ○ General*
- ☐ ○ Adjustment Assistance
- ☐ ○ Antidumping
- ☐ ○ Balance of Payments
- ☐ ○ Export Controls
- ☐ ○ Exports
- ☐ ○ Foreign Investment
- ☐ ○ Imports
- ☐ ○ Tariffs & Customs

TRANSPORTATION:
- ☐ ○ General*
- ☐ ○ Air
- ☐ ○ Highways & Motor Vehicles
- ☐ ○ Maritime
- ☐ ○ Mass Transit
- ☐ ○ Pipelines
- ☐ ○ Railroad
- ☐ ○ Safety
- ☐ ○ Tourism

VETERANS:
- ☐ ○ General*
- ☐ ○ Institutions
- ☐ ○ Pensions
- ☐ ○ Special Assistance

"THE LIGHTER SIDE" OF THE RECORD:
- ☐ A Free Selection for those who can use an occasional chuckle

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* "General" categories are furnished without charge when other topics under the main heading are selected. If you do not check them, CSI will include those which are felt essential to your subject interests, as indicated by your other selections.

IF YOU HAVE QUESTIONS ABOUT SUBJECT CONTENT OR COVERAGE, PLEASE CALL (202) 546-5800

Figure 4-3

As stated earlier, the hard copy version of CSI's Federal Register Report is published daily. The on-line file, however, is updated weekly and plans call for daily updates eventually. The on-line file covers March 1977, to the present and contains 18,000 records, however, their tapes exist from January 1977. Each weekly update is expected to include 1500 records. The cost via ORBIT for searching is $80 per connect hour and $.15 per citation for off-line printing. The cost of a subscription to CSI's hardcopy Federal Register, permitting the inclusion of up to eight topics in a profile, is $300 annually.

4.4.2 Environment Information Center, Inc.

The primary objective of this New York based firm is to function as a clearinghouse for environmental information. In order to pursue this endeavor, they market several products which are specific to the scope and requirements of a CRGS:

a. The Environment Regulation Handbook (ERH) which covers the period 1972 to the present, aims to provide information required for compliance with laws, regulations, test methods, and permit applications. ERH does not however, currently monitor FDA regulations. Updates are prepared monthly with special notice given to proposed rulemaking which may become finalized within the next month. The full text of important laws are reprinted. Volume 4 of the ERH contains state laws and regulations. The Index is fairly comprehensive, but not chemical-specific, and it is updated quarterly. ERH costs $490 the first year which includes the back files and monthly updates; subscription every year thereafter is $215.

b. STATEFICHE is a thorough collection of the environmental legislation in the fifty states and the District of Columbia. Begun in 1973, it now includes nearly 2000 documents. Liaisons or contacts are maintained to monitor the statutory events in each state. The printed index, updated semi-annually, is structured in a specific topical form, and by state. The KEYTERM LIST appears in Figure 4-4. A full initial set costs $6000, with successive years costing $3000.

C. ENVIROLINE is an on-line bibliographic data base of the literature pertaining to the environment, ranging from Air Pollution to Transportation to Weather Modification and Geophysical Change. Included in each file record are title, author, CAS number (where available), document type, source document, and the author's affiliation. Searching is done on a free-text basis, by data elements, and by index term. Samples from the EIC Keyword List appear in Figures 4-5 The total number of terms now used is between 450-500. The hard copy version of ENVIROLINE is Environment Abstracts which is published monthly. ENVIROLINE is available through SDC or Lockheed for $90 connect hour and charges are $.20/page for off-line printing.

d. Environment Abstracts and Energy Abstracts are both monthly publications which monitor the literature in their respective subject areas. Informative abstracts are written for each citation. Indexes appear in each monthly issue and are cumulated annually. Entry

KEYTERM LIST

AGRICULTURAL WASTES
AIR BASINS
AIR EMERGENCIES
AIR POLLUTION, ADMIN PROCEDURES
AIR POLLUTION CONTROL EQUIPMENT
AIR POLLUTION, EVAPORATIVES
AIR POLLUTION, GENERAL STAND
AIR POLLUTION, INDIRECT SOURCES
AIR POLLUTION, VARIANCES
AIR POLLUTION, VISIBLE EMISSIONS
AIR QUALITY, AMBIENT
AIR STANDARDS, INTERSTATE
BEVERAGE CONTAINERS
CEMENT PLANTS
COAL
COASTAL ZONE MANAGEMENT
COMMUNITY DEVELOPMENT
DETERGENTS & SOAPS
DIESEL EXHAUST EMISSIONS
DRILLING
ECONOMIC POISONS
EFFLUENT DISCHARGE
EMINENT DOMAIN
EROSION CONTROL
FORESTS & TIMBER
FUEL ADDITIVES
FUNDING
GRANT PROGRAMS
GROUND WATER
HAZARDOUS WASTES, GENERAL STAND
INCINERATORS
INDUSTRIAL WASTES
JUNK AUTOS
JUNKYARDS
LANDFILLS
LAND RECLAMATION
LAND USE, ADMIN PROCEDURES
LAND USE PLANNING
LAND USE STANDARDS
LAW ENFORCEMENT
LITTER
MINING
MOBILE SOURCE EMISSIONS
MOBILE SOURCE EQUIPMENT
MOBILE SOURCE TESTING
NATURAL GAS REGULATIONS
NAT POLL DISCHARGE ELIM SYS
NEW SOURCE EMISSIONS
NOISE STANDARDS
NOISE, MOBILE SOURCE
OCCUPATIONAL HAZARDS
ODORS
OIL REGULATIONS
OPEN BURNING
PARTICULATES
PEST CONTROL
PESTICIDE ADMIN PROCEDURES
PESTICIDE APPLICATION
PESTICIDE DEALERS
PESTICIDE DISPOSAL
PESTICIDE STANDARDS
PROTECTED LANDS & WATERS
RADIATION EQUIPMENT
RADIATION MATERIAL
RADIATION WASTE
RADIATION STANDARDS
REFUSE DISPOSAL
RESOURCE RECOVERY
RESTRICTED SUBSTANCES
SCENIC PRESERVATION
SEPTIC TANKS
SITING
SOLID WASTE, ADMIN PROCEDURES
SOLID WASTE DISPOSAL
SOLID WASTE MANAGEMENT
SOLID WASTE STANDARDS
SOLID WASTE TRANSPORT
SPILLS OIL/ETC
STATIONARY SOURCE EMISSIONS
STATIONARY SOURCE EQUIPMENT
STATIONARY SOURCE TESTING
STRIP MINING
TAX EXEMP POLL EQUIPMENT
THERMAL DISCHARGES
WASTEWATER OPERATOR CERTIF
WASTEWATER TREATMENT
WATER BASINS
WATER CLASSIFICATION
WATERCRAFT SANITARY SYSTEMS
WATER, DRINKING
WATER, INTERSTATE
WATER POLLUTION, ADMIN PROCEDURES
WATER QUALITY, INLAND
WATER QUALITY MANAG & STAND
WATER QUALITY, OCEANS
WETLANDS MANAGEMENT
WILDLIFE
ZONING & SUBDIVISIONS

Figure 4-4

EIC KEYTERM LIST

BOSCH PROCESS
BOSTON
BOSTON UNIV
BOTANIC GARDENS
BOTANY
BOTSWANA
BOTTLED GAS
BOTTOMING CYCLES
BOUNDARY WATERS CANOE AREA
BOY SCOUTS
BRAHMAPUTRA RIVER
BRAHMAPUTRA RIVER BASIN
BRASILIA
BRAYTON CYCLES
BRAZIL
BRAZZAVILLE
BREAST FEEDING
BREEDER REACTORS
BREMSSTRAHLUNG
BRIDGES
BRINEGAR, CLAUDE S
BRISTOL BAY
BRITISH COLUMBIA
BRITISH COLUMBIA, UNIV
BRITISH COMMONWEALTH
BRITISH GAS CORP
BRITISH HONDURAS
BRITISH LEYLAND MOTOR CORP
BRITISH PETROLEUM CO
BRITISH STEEL CORP
BROMETHRIN
BROMIDES
BROMINE
BRONCHITIS
BROOKINGS INST
BROOKLYN COLLEGE
BRUNEI
BRUSSELS
BRYCE CANYON NATL PARK
BUCHAREST
BUDAPEST
BUDDHISM
BUDGETS, INTL
BUDGETS, NON U S
BUDGETS, STATE LOCAL
BUDWORMS
BUENOS AIRES
BUFFALO
BUFFALO, N Y
BUFFALO, UNIV
BUHL FOUNDATION
BUILDING AGE
BUILDING CODES
BUILDING DESIGN
BUILDING SIZE
BUILDINGS
BUILDUP RATES
BULGARIA
BULK TERMINALS
BULKING
BUNKER C FUEL OIL
BURMA
BURUNDI
BUS EMISSION CONTROL
BUS EMISSIONS
BUS ENERGY USAGE
BUS NOISE
BUS NOISE CONTROL
BUS TRANSPORTATION
BUSBARS
BUTADIENE
BUTANE
BUTTERFLIES
BUTYLATE
BUTYLENE
BUTZ, EARL L.
BYSSINOSIS
CABBAGE
CABINDA
CACTUS
CADMIUM
CADMIUM COMPOUNDS
CADMIUM 109
CADMIUM 115
CAIRO
CALCIUM
CALCIUM CHLORIDE
CALCIUM COMPOUNDS
CALCUTTA
CALIFORNIA
CALIFORNIA ENV QUALIT ACT 70
CALIFORNIA INST TECHNOLOGY
CALIFORNIA WATER PROJECT
CALIFORNIA, UNIV
CALIFORNIUM
CAMBODIA
CAMBRIDGE UNIV
CAMELS
CAMEROON
CAMP FIRE GIRLS
CAMPING
CANADA
CANADA DEPT ENV
CANADA ENV PROTECT SERVICE
CANADA NATL ENERGY BOARD
CANADIAN CNCL RES ENV MINSTS
CANADIAN PETROLEUM ASSN
CANALS
CANARY ISLANDS
CANDU REACTORS
CANNERIES
CAPACITANCE
CAPACITOR BANKS
CAPE HATTERAS
CAPITAL COSTS
CAPITAL GAINS
CAPITAL INTENSIVENESS
CAPITALISM
CAPTAN
CAR POOLS
CARACAS
CARBAMATE PESTICIDES
CARBARYL
CARBIDES
CARBON
CARBON BLACK
CARBON DIOXIDE
CARBON DIOXIDE ACCEPTOR PROCESS
CARBON MONOXIDE
CARBON OXIDES
CARBON TETRACHLORIDE
CARBON 14
CARBONIZATION
CARBORUNDUM CO
CARBOXYHEMOGLOBIN
CARCINOGENIC AGENTS
CARIBBEAN ISLANDS
CARIBBEAN SEA
CARLSBAD CAVERNS
CARLSBAD CAVERNS NATL PARK
CARNEGIE CORP
CARNEGIE INST TECHNOLOGY
CAROLINE ISLANDS
CARP
CARRYING CAPACITY
CARRYOVER EFFECT
CARSON, RACHEL
CARTELS
CARTOGRAPHY
CASABLANCA
CASCADE IMPACTORS
CASCADE RANGE
CASPIAN SEA
CAT—OX PROCESS
CATALYSTS
CATALYTIC CONVERTERS
CATALYTIC CRACKING
CATALYTIC HYDROGEN PROCESS
CATALYTIC HYDROGENATION COAL TAR
CATALYTIC REFORMING
CATERPILLAR TRACTOR CO
CATFISH
CATHOLICISM
CATSKILL MOUNTAINS
CATTLE
CELLULOSE
CELTIC SEA
CEMENT
CEMETERIES
CENSUS
CENTER LATIN AMER DEMOGRAPHY
CENTIPEDES
CENTRAL AFRICA
CENTRAL AFRICAN REPUBLIC
CENTRAL AMERICA
CENTRAL ASIA
CENTRALIZED ENERGY SYSTEMS
CENTRIFUGES
CERIUM
CERIUM 141
CERIUM 144
CESIUM
CESIUM 134
CESIUM 136
CESIUM 137
CESSPOOLS
CHAD
CHAINING
CHANNEL ISLANDS
CHANNELIZATION
CHAR
CHARCOAL
CHARLES RIVER
CHARLES RIVER BASIN
CHEETAHS
CHELATING AGENTS
CHEM POLL CONT FINANCING
CHEM POLL CONT INVESTMENT
CHEMICAL CONTAM
CHEMICAL CONTAM CONTROL
CHEMICAL CONTROL
CHEMICAL CONTROL—FUNGI
CHEMICAL CONTROL—INSECTS
CHEMICAL CONTROL—PESTS
CHEMICAL CONTROL—WEEDS
CHEMICAL DAMAGE
CHEMICAL ENERGY
CHEMICAL INDICATORS
CHEMICAL INDICATORS—AIR
CHEMICAL INDICATORS—MARINE
CHEMICAL INDICATORS—WATER
CHEMICAL NEUTRALIZATION
CHEMICAL OXYGEN DEMAND
CHEMICAL PRECIPITATION
CHEMICAL PURIFICATION
CHEMICAL REDUCTION
CHEMICAL RESIDUES
CHEMICAL SHORTAGE
CHEMICAL SPILLS
CHEMICAL STANDARDS
CHEMICAL STORAGE
CHEMICAL TRANSPORT
CHEMICAL TREATING
CHEMICAL TREATMENT
CHEMICAL USAGE
CHEMICAL WASTES
CHEMICAL, BIOLOGICAL CONFS
CHEMICAL, BIOLOGICAL WARFARE
CHEMILUMINESCENCE
CHEMISORPTION
CHEMOSTERILANTS
CHESAPEAKE BAY
CHICAGO
CHIHUAHUAN DESERT
CHILE
CHILLING
CHINA
CHLORATES
CHLORDANE
CHLORFENVINPHOS
CHLORIDES
CHLORINATED DIBENZODIFURANS
CHLORINATED DIBENZODIOXINS
CHLORINATED HYDROCARBONS
CHLORINATED PARAFFINS
CHLORINATION
CHLORINE
CHLORINE DIOXIDE
CHLORINE 36
CHLORINOLYSIS
CHLORO IPC
CHLOROFLUOROMETHANES
CHROMATES
CHROMATOGRAPHY
CHROMATOGRAPHY, GAS
CHROMATOGRAPHY, PAPER
CHROMATOGRAPHY, REVERS PHASE
CHROMATOGRAPHY, THIN LAYER
CHROMIUM
CHROMIUM COMPOUNDS
CHROMIUM REFINING
CHROMIUM RESOURCES
CHROMIUM WASTES
CHROMIUM 51
CHRYSLER CORP
CIGARETTE SMOKE
CINCINNATI
CINCINNATI, UNIV
CIRCUITS
CITIES
CITIES SERVICE OIL CO
CITRUS FRUITS
CITY UNIV NEW YORK
CLAMS
CLARIFICATION
CLASSICAL CONFINEMENT
CLAUS PROCESS
CLEAN AIR ACT 70
CLEAN WATER RESTORE ACT 72
CLEARCUTTING
CLEVELAND
CLIMATE CONTROL
CLIMATIC CHANGES
CLIMATIC COMPARISONS
CLIMATOLOGY
CLIMATOLOGY CONFS
CLIMAX COMMUNITIES
CLOSED ECOLOGICAL SYSTEMS
CLOUD SEEDING
CLOUDS
CLUB OF ROME
COAGULATION
COAL
COAL ALKYLATION
COAL ANALYSIS
COAL BLENDING
COAL CHEMISTRY
COAL CLASSIFICATION
COAL CLEANING
COAL CONSERVATION
COAL CONSERVATION—REGION
COAL CONSERVATION—SECTOR
COAL CONSERVATION, AGRI
COAL CONSERVATION, COMMERCIAL
COAL CONSERVATION, DOMESTIC
COAL CONSERVATION, GOVT
COAL CONSERVATION, INDUSTRIAL
COAL CONSERVATION, PER CAPITA
COAL CONSERVATION, TRANSPORT
COAL DEMAND
COAL DEMAND—REGION
COAL DEMAND—SECTOR
COAL DEMAND, AGRICULTURAL
COAL DEMAND, COMMERCIAL
COAL DEMAND, DOMESTIC
COAL DEMAND, GOVT
COAL DEMAND, INDUSTRIAL
COAL DEMAND, PER CAPITA
COAL DEMAND, TRANSPORT

Figure 4-5

is by author and subject. Conference proceedings, reports, speeches, as well as published materials, are all included in their scopes. They are available by subscription for $350 and $375 per year respectively.

4.4.3 Environmental Law Reporter

This is a monthly publication of the Environmental Law Institute (ELI) which covers litigation of the federal and state courts as well as federal statutes and regulations, and relevant international treaties and conventions. Cases appear either in digest or full text format. A case listed in digest form incorporates the briefs, arguments, and of course, the decision itself. If the case appears as full text, a concise headnote precedes the text of the decision. Pending litigation documentation is included in the Reporter as well.

The "finding aids" or indexes developed by ELI are a Cumulative Table of Cases Published in ELR, and a Subject Matter Index which does not include a chemical name, but provides entry by a general use category, such as Solid Waste, or Land Use.

4.4.4 Bureau of National Affairs (BNA)

BNA publishes several reporting services in different subject areas. Of 52 publications, five of them pertain to a CRGS:

- Chemical Regulation Reporter
- Environment Reporter
- International Environment Reporter
- Occupational Safety and Health Reporter
- Product Safety and Liability Reporter

At present, there are no plans for initiating a "Food and Drug Reporter." More than monitoring and compiling the Federal Register or regulatory agency enforcement actions, this firm reports on the action, discusses its impact, and how a policy is being implemented. Each "Reporter" is a separate publication with its own editor. There is no computer assistance in-house, but their typesetting is done by computer through a subcontract. In general, there is a six week lag time between the issuance of a regulation and its appearance in the "Reporter," although it is published weekly.

The relevant "Reporters" are discussed individually below:

a. "Environment Reporter" - a weekly review of pollution control and related environmental management problems. It is composed of several sections of which three pertain to a CRGS: Current Developments which covers legislation, regulations, standards, enforcement, and research activities; Reference File which includes the full text of Federal laws, and State Air, Water, Solid Waste, and Land Use laws; and Court Decisions. The Current Developments Section is itself divided into the topical areas of Air Pollution, Water Pollution, etc. An index appears quarterly which is not chemical-specific. Court Decisions are accessed in several ways: by broad topics such as Air Quality Standards and Pesticides; by case name; a table of cases by jurisdiction; and a classification scheme, devised by BNA, which facilitates access to related points of case law. An example of the hierarchy is given below:

STATUTES
    FEDERAL
        CLEAN AIR ACT
            HAZARDOUS EMISSION STANDARDS

b. "Chemical Regulation Reporter" - a weekly review of chemical regulations which includes testing and reporting rules, implementation of TSCA and the Resource Conservation and Recovery Act, packaging and shipping requirements for hazardous materials as adopted by DOT, and legislative and industrial activity. This Reporter is divided into a Current Reports and a Reference File, the former consisting of highlights and the reporting of actions, and the latter containing the full text of statutes, regulations, and policies. The index is chemical-specific.

c. "International Environmental Guide" - essentially a reference file which includes the full text of treaties, bilateral agreements, European Economic Community Directives (e.g., Convention for the Prevention of the Rhine Against Chemical Pollution), and the internal laws of foreign countries which relate to the environment. This volume is indexed by country and topical subjects (e.g., Air Pollution, Water Quality).

d. "Occupational Safety and Health Reporter" - a weekly review of the activities of the Occupational Safety and Health Review Commission (OSHRC), the Occupational Safety and Health Administration, and NIOSH. "Current Reports" monitors regulations, standards, public testimony, enforcement actions (including inspections, citations, penalties, and rulings), research, legislation, and union activities. "Reference File" reprints the full text of the items listed above as well as directories of personnel in the related government agencies and advisory panels. State-level plans and regulations are monitored in this "Reporter" also. The Index is cumulative and is chemical-specific at the second level only, that is, entry is first through "Chemicals and Chemical Industry" and the specific chemicals are subheadings. "Decisions" monitors the courts and OSHRC rulings. Material appears in full text for all significant decisions as well as with headnotes. There are multiple access points: docket number; topical index; table of cases; and a master standards index.

e. "Product Safety and Liability Reporter" - a weekly publication of current information related to product safety, with particular emphasis on the administration, implementation, and enforcement of the Consumer Product Safety Act. "Current Reports" reviews the activities of the CPSC and relevant court decisions on product liability. "Reference File" reprints the full text of laws administered by CPSC (Flammable Fabrics Act, Poison Prevention Packaging Act), the full text of product safety standards including performance standards, descriptive standards, and labeling and packaging standards. Regulations pertaining to inspection, resting, recordkeeping are also printed in full, as are enforcement actions. A directory pf personnel in government agencies involved with consumer product safety appears in this section also. Both of these sections have Indexes.

4.4.5 Information Handling Services

This firm, based in Englewood, Colorado, is involved in supplying industry, government, and educational institutions with technical information on microfilm. This ranges from military specifications to federal construction regulations to industry standards and vendor product data to state laws and regulations, and court cases from the Supreme Court and the U.S. Court of Claims. In many cases, they have organized this mass of information with extensive, detailed indexing schemes which facilitates access to particular documents. All their sources are available on microfilm, however, the respective indexes are often also hard copy publications. The specific products which are pertinent to a CRGS are enumerated and discussed below:

1. Code of Federal Regulations 1938-1976 is available in microfiche, either in its entirety, by the current decade (1970-1976), by individual Title, or by year. Continuing updates are planned as a new Code becomes available which is every three to four months. An index to the CFR is currently in preparation with two Titles already in print (Titles 10 and 40). The indexing project was separated into sigments by Title to make it more manageable, but a cumulative index is planned for 1979. The index is divided into four sections: subject, geographic, list of descriptive headings, and list of reserved headings. The citation includes the chapter, subchapter, part, subpart, page and notation if tables or illustrations are given. Within the subject index section, specificity is a primary consideration so that chemical-specific access is available. Similarly, generic access is also possible. Subject entries are further modified to account for specific aspects. For example, two sample entries follow:

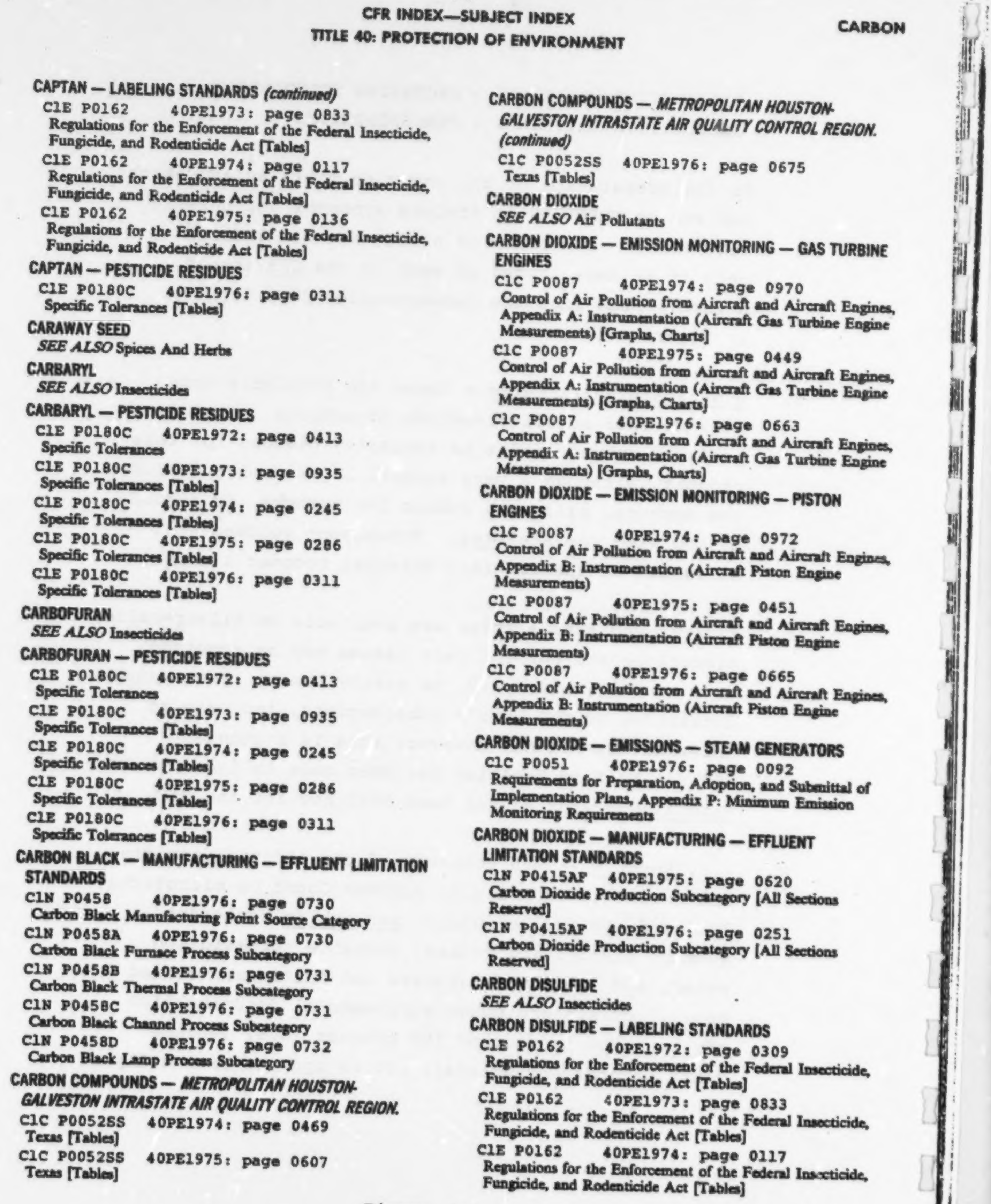
RADIOACTIVE MATERIALS - PACKAGING STANDARDS
RADIOACTIVE MATERIALS - TRANSPORTATION

In the preparation of the Index to Title 40, a search was run on CHEMLINE to include synonyms and generic references. A product or brand name was indexed only if it were listed as such in the CFR itself. A sample page from the Demonstration Copy appears in Figure 4-6.

2. U.S. Statutes at Large - These are available from 1789 to 1975 on silver-halide microfiche. No IHS-produced subject index is currently planned for this product, although a very general index which includes the dockets, bill, and Public Law numbers, is issued by GPO with the Statutes. Subsequent volumes will be issued as the original material becomes available.

3. Federal Register - These are available on silver-halide microfiche and current year issues may be acquired on a monthly, quarterly, or yearly basis. Each volume, consisting of one year's publications, includes an index on microfiche, however, this is a general index. No firm decision has been made to index the Federal Register as has been outlined for the CFR.

4. U.S. Reports - This consists of the official reports and decisions of the U.S. Supreme Court on microfiche. Included are full opinions, per curiam decisions, summary disposition orders, probable jurisdiction noted, and certiorari granted and certiorari denied cases. Briefs and other supplemental documentation may be found in another IHS product (U.S. Supreme Court Records and Briefs). It is updated biannually



CFR INDEX—SUBJECT INDEX
TITLE 40: PROTECTION OF ENVIRONMENT
CARBON

CAPTAN — LABELING STANDARDS *(continued)*
C1E P0162 40PE1973: page 0833
Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act [Tables]
C1E P0162 40PE1974: page 0117
Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act [Tables]
C1E P0162 40PE1975: page 0136
Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act [Tables]

CAPTAN — PESTICIDE RESIDUES
C1E P0180C 40PE1976: page 0311
Specific Tolerances [Tables]

CARAWAY SEED
SEE ALSO Spices And Herbs

CARBARYL
SEE ALSO Insecticides

CARBARYL — PESTICIDE RESIDUES
C1E P0180C 40PE1972: page 0413
Specific Tolerances
C1E P0180C 40PE1973: page 0935
Specific Tolerances [Tables]
C1E P0180C 40PE1974: page 0245
Specific Tolerances [Tables]
C1E P0180C 40PE1975: page 0286
Specific Tolerances [Tables]
C1E P0180C 40PE1976: page 0311
Specific Tolerances [Tables]

CARBOFURAN
SEE ALSO Insecticides

CARBOFURAN — PESTICIDE RESIDUES
C1E P0180C 40PE1972: page 0413
Specific Tolerances
C1E P0180C 40PE1973: page 0935
Specific Tolerances [Tables]
C1E P0180C 40PE1974: page 0245
Specific Tolerances [Tables]
C1E P0180C 40PE1975: page 0286
Specific Tolerances [Tables]
C1E P0180C 40PE1976: page 0311
Specific Tolerances [Tables]

CARBON BLACK — MANUFACTURING — EFFLUENT LIMITATION STANDARDS
C1N P0458 40PE1976: page 0730
Carbon Black Manufacturing Point Source Category
C1N P0458A 40PE1976: page 0730
Carbon Black Furnace Process Subcategory
C1N P0458B 40PE1976: page 0731
Carbon Black Thermal Process Subcategory
C1N P0458C 40PE1976: page 0731
Carbon Black Channel Process Subcategory
C1N P0458D 40PE1976: page 0732
Carbon Black Lamp Process Subcategory

CARBON COMPOUNDS — *METROPOLITAN HOUSTON-GALVESTON INTRASTATE AIR QUALITY CONTROL REGION.*
C1C P0052SS 40PE1974: page 0469
Texas [Tables]
C1C P0052SS 40PE1975: page 0607
Texas [Tables]

CARBON COMPOUNDS — *METROPOLITAN HOUSTON-GALVESTON INTRASTATE AIR QUALITY CONTROL REGION. (continued)*
C1C P0052SS 40PE1976: page 0675
Texas [Tables]

CARBON DIOXIDE
SEE ALSO Air Pollutants

CARBON DIOXIDE — EMISSION MONITORING — GAS TURBINE ENGINES
C1C P0087 40PE1974: page 0970
Control of Air Pollution from Aircraft and Aircraft Engines, Appendix A: Instrumentation (Aircraft Gas Turbine Engine Measurements) [Graphs, Charts]
C1C P0087 40PE1975: page 0449
Control of Air Pollution from Aircraft and Aircraft Engines, Appendix A: Instrumentation (Aircraft Gas Turbine Engine Measurements) [Graphs, Charts]
C1C P0087 40PE1976: page 0663
Control of Air Pollution from Aircraft and Aircraft Engines, Appendix A: Instrumentation (Aircraft Gas Turbine Engine Measurements) [Graphs, Charts]

CARBON DIOXIDE — EMISSION MONITORING — PISTON ENGINES
C1C P0087 40PE1974: page 0972
Control of Air Pollution from Aircraft and Aircraft Engines, Appendix B: Instrumentation (Aircraft Piston Engine Measurements)
C1C P0087 40PE1975: page 0451
Control of Air Pollution from Aircraft and Aircraft Engines, Appendix B: Instrumentation (Aircraft Piston Engine Measurements)
C1C P0087 40PE1976: page 0665
Control of Air Pollution from Aircraft and Aircraft Engines, Appendix B: Instrumentation (Aircraft Piston Engine Measurements)

CARBON DIOXIDE — EMISSIONS — STEAM GENERATORS
C1C P0051 40PE1976: page 0092
Requirements for Preparation, Adoption, and Submittal of Implementation Plans, Appendix P: Minimum Emission Monitoring Requirements

CARBON DIOXIDE — MANUFACTURING — EFFLUENT LIMITATION STANDARDS
C1N P0415AF 40PE1975: page 0620
Carbon Dioxide Production Subcategory [All Sections Reserved]
C1N P0415AF 40PE1976: page 0251
Carbon Dioxide Production Subcategory [All Sections Reserved]

CARBON DISULFIDE
SEE ALSO Insecticides

CARBON DISULFIDE — LABELING STANDARDS
C1E P0162 40PE1972: page 0309
Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act [Tables]
C1E P0162 40PE1973: page 0833
Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act [Tables]
C1E P0162 40PE1974: page 0117
Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act [Tables]

Figure 4-6

and is dependent upon the initial publication by the GPO. A general subject index with case names is provided but IHS does not furnish any "extra" indexing.

5. State Session Laws, 1970-1976 - This includes all the state statutes, and is available on microfiche produced from the original official documents. All 50 states, the Virgin Islands, and Puerto Rico are covered. The existing indexes, as made available by the state, are included on the microfiche. However, an index whose specificity is still to be determined has been considered. The general plan is to divide the U.S. into clusters and publish an index for each cluster with the initial coverage being 1970-1976. The first segment of the Index, which will be in hard copy, is expected sometime in 1979. Since IHS considers the executive branch to be more specific in their regulations than the legislative branch, compatibility with the CFR Index will be necessarily limited. This product is updated on a semi-annual basis and its currency is dependent upon the state publications schedules.

4.5 Comparison of Existing Capabilities

From the descriptions of systems discussed in the preceding section, it is apparent that there are several existing services which must be evaluated in more detail to determine the optimal method(s) for development and implementation of a CRGS. Before any alternatives are presented, the user requirements, as summarized in Section 2.3 must be matched against the capabilities available under existing systems.

Source Material Evaluation was discussed in Section 4.4 and a summary table was presented in Table 4-1. The collection or holding of source material was considered to be the primary criterion upon which systems were chosen for evaluation in this study. However, this requirement is reviewed in the summary evaluation and further discussed in this section.

The following section will evaluate the systems discussed in Section 4.4 and JURIS (Section 4.3.3) in order to determine which sources might be best utilized and/or enhanced for the implementation of a CRGS. While no source currently meets all the user requirements, there are several systems which approximate many of them. Table 4-7 summarizes the primary user requirements with the added consideration of the availability of a machine-readable format capability. Having information in a machine-readable format obviously increases the capacity for flexibility, which in the potential adaptation of an existing system, is highly advantageous.

The primary user requirements which have been used to rank the existing sources are:

- Access Capabilities - essentially refers to search mechanisms, of which the most is important chemical-specific access. If the entry point were a general use category (solid waste, water pollution), a value of 1 was assigned; if the entry point were a chemical, a value of 2 was assigned; and if it were possible to search on a chemical and its use (free text format or as an index term), a value of 3 was assigned.

- Current Awareness - refers to the frequency of update. 0 was given for yearly; 1 for monthly; and 2 for weekly or more.
- Content - refers to the inclusion of more than a "bibliographic" citation to a law or regulation. 0 was given for None, or full text, and 1 was given for an abstract.
- Source Document Coverage - rated on the basis of inclusion of Federal regulations and laws, court decisions, and state laws. For example, since CSI monitors federal regulations and statutes, 2 points were scored. Since BNA covers court decisions, statutes, and regulations with the exception of FDA, only 2 points were given. The overall source document coverage of existing systems is displayed in Table 4-1.
- Machine-readable Format - while not stated as a user requirement per se, when analyzing the adaptation and/or enhancement of existing systems, this element becomes a valuable asset because it permits a large degree of flexibility. Therefore a value of 1 was assigned if the information existed in a machine-readable format.

In preliminary discussions with CSI, EIC, BNA, and IHS in which they were informed of the development of a CRGS, they all expressed interest in enhancing their present capabilities to meet the primary requirements of a CRGS. However, the enhancements needed for their respective systems varied considerably. Table 4-7 represents not only the comparative evaluation of six systems, but also reflects the degree of effort which would be needed for modification of the existing systems to conform to the primary requirements of CRGS.

EVALUATION OF EXISTING CAPABILITIES

TABLE 4-7

	Access Capabilities	Current Awareness (Update)	Content	Source Document Coverage	Machine-Readable Format	TOTAL
CSI	3	2	1	2	1	9
EIC	3	1	1	2	0	7
ELI	1	1	0[d]	3	0	5
BNA	2[a]	2[c]	0	2	0	6
IHS	3[b]	0	0	4	0	7
JURIS	3	2	0[d]	3	1	9

a - not in all publications

b - hardcopy index in development

c - six week time lag

d - headnotes not considered equal with abstracts

ELI ranks low because of its limited access and because it reproduces the full text of documents. Headnotes (which are briefs, arguments, and the decision in digest form) are included but these were considered to be too much information for the pruposes of a CRGS. In fact, they tend to be more closely related to a full text format than an abstract. ELI does not monitor state laws and regulations, and therefore it was given a value of 3 (out of a maximum of 4) in its source document coverage. BNA also received a low ranking because it indexes only one of its "reporters" on a chemical-specific basis ("Chemical Regulation Reporter") and because there is no coverage of FDA regulations, nor is it planned. This latter point is a serious deficiency which skews the results appearing in Table 4-1. Also, the Current Developments Section of each BNA Reporter actually reports on the regulations, their impact, and how they reflect policy. The emphasis is more on comprehensive articles rather than on simply stating the measures needed to comply with the law. Therefore, in Content, BNA was given a value of 0 since it presently does not provide an abstracting capability.

On the basis of Table 4-7, it was determined that ELI and BNA did not qualify for further discussion in terms of options for implementation. The kinds of developments required in these two systems would be both time-consuming and expensive, especially when there are other sufficient alternatives for the implementation of a CRGS. In Section 5.0, Sigma Data will examine the implementation options for the existing systems, which from the discussion above, seem to offer the greatest potential for the development of a CRGS.

4.6 Existing Subject Classification Schemes

In 1977, Auerbach Associates, under contract to EPA, developed a classification scheme to allow manufacturers, processors, and importers of chemicals to report information in a manner which would assist EPA in carrying out its responsibilities under TSCA. Two lists which are applicable to a thesaurus for a CRSG are the Function List and the Application List.

The Function List contains descriptors which represent specific actions for which chemicals are used. The Application List contains descriptors pertaining to those processes or products in which chemical substances are used. For example, a chemical may function as a sweetener for application to chewing gum. Or, a chemical may function as a dye retardant in apparel. Each report submitted by industry requires coding from both of these lists.

The Classification System is extensively cross-referenced and arranged in a hierarchical manner. Samples from the Indexes to the Lists and the Classification Systems appear in Figures 4-8. Although this system was developed for EPA, there is coverage in areas which correspond to the jurisdictions of the other IRLG agencies. Thus, there are extensive listings under "Food and Kindred Products" and "Consumer and Commercial Applications." However, there are gaps in areas such as Labeling, Transportation, Packaging, and Recordkeeping. Nonetheless, the Auerbach Classification System can serve as a strong foundation for the coding of document records in a CRGS.

In the course of designing the CSIN Directory (or the Chemical Data Bases Directory, CDBD), the Metrek Division of the MITRE Corporation is developing a system vocabulary of standardized terms designating the subjects of interest in the CSIN.[1] The subject categories include, but are not

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[1] "Design and Structure of the CSIN Directory" Working Paper - 12947 of the MITRE Corporation Metrek Division. Contract No. CEQ 7A010

EPA CLASSIFICATION SYSTEM: INDEX TO LIST I 97

DUSTING AGENTS (RUBBER TECHNOLOGY) 191

DYE ASSISTANTS
  SEE: DYE CARRIERS 1100
    DYE DEVELOPERS 1740
    DYE INTENSIFIERS 2610
    DYE LEVELING AGENTS 2690
    DYE RESERVING AGENTS 192
    DYE RETARDANTS 193
    DYE RETENTION AIDS 194
    FIXATIVES 219
    MORDANTS 278

DYE CARRIERS 1100

DYE DEVELOPERS 1740

DYE FIXATIVES
  SEE: FIXATIVES 219

DYE INTENSIFIERS 2610

DYE LEVELING AGENTS 2690

DYE RESERVING AGENTS 192

DYE RETARDANTS 193

DYE RETENTION AIDS 194

DYE STRIPPERS 3580

DYES 1330

EAR PREPARATIONS
  SEE: OTIC PREPARATIONS 292

ELECTRICAL INSULATING COMPOUNDS 2601

ELECTROLYTES 195

ELECTROPLATING RESISTS
  SEE: RESISTS 323

ELUTING AGENTS 196

EMETICS 197

EMOLLIENTS 198

EMULSIFIERS 3622

Figure 4-8(1)

EPA CLASSIFICATION SYSTEM: LIST I (FUNCTION)

355	STAINS
356	STARCH IMPROVERS
357	STIFFENING AGENTS
358	STRIPPERS
3580	DYE STRIPPERS
3581	PAINT STRIPPERS
3582	WAX STRIPPERS
359	STRUCTURAL BINDERS (COMPOSITIONS USED IN THE BUILDING TRADES TO CEMENT STRUCTURAL ELEMENTS TOGETHER)
360	STRUCTURAL COMPONENTS (MATERIALS USED IN THE BUILDING TRADES AS STRUCTURAL ELEMENTS)
361	SURFACE FINISHING AGENTS (SUBSTANCES USED TO INCREASE PALATABILITY, PRESERVE GLOSS AND INHIBIT DISCOLORATION OF FOODS, INCLUDING GLAZES, POLISHES, WAXES AND PROTECTIVE COATINGS)
362	SURFACTANTS
3620	DETERGENTS (INCLUDES SOAPS AND SYNTHETIC DETERGENTS)
3621	DISPERSNATS (AGENTS ADDED TO A SUSPENDING MEDIUM TO PROMOTE UNIFORM SEPARATION OF EXTREMELY FINE SOLID PARTICLES, OFTEN OF COLLOIDAL SIZE)
3622	EMULSIFIERS (AGENTS WHICH HOLD IN SUSPENSION A STABLE MIXTURE OF TWO OR MORE IMMISCIBLE LIQUIDS)
3623	FLOTATION AGENTS
3624	PENETRANTS (COMPOUNDS USED TO INCREASE THE SPEED AND EASE WITH WHICH A BATH OR LIQUID PERMEATES A MATERIAL BEING PROCESSED BY EFFECTIVELY REDUCING THE INTERFACIAL TENSION BETWEEN THE SOLID AND LIQUID)
3625	RINSE AIDS
3626	SOIL SUSPENDING AGENTS (COMPOUNDS USED IN LAUNDRY AND DRYCLEANING PRODUCTS TO PREVENT REDEPOSITION OF SOIL ON LAUNDRY)
3627	WETTING AGENTS.
363	SWELLING AGENTS
364	TACKIFIERS
365	TANNING AGENTS
3650	BATES

Figure 4-8(2)

EPA CLASSIFICATION SYSTEM: INDEX TO LIST II

- CATSUP
  - SEE: CANNED FRUITS AND VEGETABLES 0970
- CATTLE PRODUCTION
  - SEE: BEEF CATTLE PRODUCTION 01510
  - DAIRY FARMING 0150
- CATTLE SPRAYING 01001
- CELLOPHANE
  - SEE: REGENERATED CELLULOSIC PRODUCTS, EXCEPT RAYON 0708
- CELLULOSE SPONGES
  - SEE: REGENERATED CELLULOSIC PRODUCTS, EXCEPT RAYON 0708
- CELLULOSIC MANMADE FIBERS 210
- CERAMIC FOOD UTENSILS 2650
- CERAMIC MINERAL MINING
  - SEE: CLAY, CERAMIC AND REFRACTORY MINERAL MINING 1531
- CERAMIC PIPE AND DRAIN TILE 2671
- CERAMIC TILE
  - SEE: BRICK AND STRUCTURAL CLAY TILE 2670
  - CERAMIC PIPE AND DRAIN TILE 2671
  - CERAMIC WALL AND FLOOR TILE 2672
- CERAMIC WALL AND FLOOR TILE 2672
- CEREAL BREAKFAST FOODS 0940
- CHEESE 0921
- CHEMICAL AND FERTILIZER MINERAL MINING 1530
- CHEMICAL AND MEDICAL TESTING 04011
- CHEMICAL MANUFACTURING AND PETROLEUM REFINING MACHINERY 1490
- CHEMICAL, TECHNICAL AND INDUSTRIAL GLASSWARE 2660
- CHEMICAL, TECHNICAL AND INDUSTRIAL POTTERY WARE 2651
- CHEMICAL WARFARE AGENTS
  - SEE: BIOLOGICAL AND CHEMICAL WARFARE AGENTS 1700
- CHEMICALS 02
  - SEE ALSO: DRUGS AND OTHER PHARMACEUTICALS 05
  - PAINT AND ALLIED PRODUCTS 18
  - PETROLEUM REFINING 20
  - PLASTIC AND RUBBER MATERIALS AND SYNTHETICS (NOT FABRICATED) 21
  - PRINTING INKS 24
  - SANITIZING AGENTS, POLISHES AND COSMETICS 25
- CHEWING GUM 0981
- CHICKEN EGG PRODUCTION 01520
- CHICKEN PRODUCTION 01521
- CHILDREN'S OUTERWEAR
  - SEE: OUTERWEAR, EXCEPT KNITTED 0802

Figure 4-8(3)

EPA CLASSIFICATION SYSTEM: LIST II

07	FABRICATED RUBBER AND PLASTIC PRODUCTS
070	MISCELLANEOUS FABRICATED PLASTIC PRODUCTS
0700	FOAMED PLASTIC PRODUCTS (INCLUDES UNCOVERED MATTRESS CORES, INSULATION AND FORMED AND SLAB STOCK FOR PILLOWS AND CUSHIONS, CUPS AND PLATES, ETC.)
0701	INDUSTRIAL PLASTIC PRODUCTS (INCLUDES PARTS AND ACCESSORIES FOR MOTOR VEHICLES, AIRCRAFT, MISSILES, APPLIANCES AND INDUSTRIAL EQUIPMENT, AS WELL AS KNIFE HANDLES, BATTERY BOXES, PLUGS, ETC. EXCLUDES BELTING, PACKING AND SEALS)
0702	LAMINATED PLASTIC SHEET, ROD AND TUBE
0703	PHONOGRAPH RECORDS AND RECORDING TAPES
0704	PLASTIC APPAREL
0705	PLASTIC DINNERWARE, TABLEWARE AND KITCHENWARE
0706	PLASTIC PACKAGING AND SHIPPING CONTAINERS (INCLUDES BOXES, BOTTLES, DRUMS, CLOSURES, BLISTER AND BUBBLE FORMED PACKAGING AND BOX LINERS; FOR PLASTIC PACKING DUNNAGE, SEE FOAMED PLASTIC PRODUCTS OR UNSUPPORTED PLASTIC FILM, SHEET, ROD AND TUBE.)
0707	PLASTIC TUBING, EXCEPT MEDICAL AND SURGICAL
0708	REGENERATED CELLULOSIC PRODUCTS, EXCEPT RAYON (INCLUDES CELLOPHANE, CAPS, BANDS AND SPONGES)
0709	UNSUPPORTED PLASTIC FILM, SHEET, ROD AND TUBE
071	MISCELLANEOUS FABRICATED RUBBER PRODUCTS
0710	MECHANICAL RUBBER GOODS (INCLUDES HARD, MOLDED, EXTRUSION AND LATHE CUT RUBBER MECHANICAL GOODS; RUBBER BOATS AND RAFTS: PRESSURE SENSITIVE TAPE, SHEET RUBBER, ROLLS AND TUBING, EXCEPT MEDICAL AND SURGICAL)
0711	RUBBER APPAREL (INCLUDES BATHING AND SHOWER CAPS, RAINWEAR, APRONS, BABY PANTS, INDUSTRIAL RUBBER GLOVES)
0712	RUBBER BALLOONS (INCLUDES TOY, ADVERTISING AND METEOROLOGICAL BALLOONS)
0713	RUBBER COATED FABRICS (INCLUDES APPAREL AND FOOTWEAR FABRICS, UPHOLSTERY FABRICS AND HOSPITAL AND CRIB SHEETING)
0714	RUBBER DRUGGIST AND MEDICAL SUNDRIES (INCLUDES HOUSEHOLD AND SURGICAL GLOVES, BOTTLES AND NIPPLES, PROPHYLACTICS, ICE BAGS, MEDICAL-SURGICAL TUBING)
0715	RUBBER FLOOR AND WALL COVERINGS
0716	RUBBER HEELS AND SOLES (INCLUDES MATS, STAIR TREADS)
0717	RUBBER STATIONERS' SUNDRIES (INCLUDES RUBBER BANDS, ERASERS AND FINGER COTS)
0718	SPONGE AND FOAM RUBBER GOODS (INCLUDES LATEX FOAM AND CHEMICALLY BLOWN SPONGE FOR PADDING, UPHOLSTERY, MATTRESS CORES, PILLOWS AND INSULATION)
0719	UNSUPPORTED RUBBER FILM AND SHEETING

Figure 4-8(4)

limited to: Production Factors; Uses/Users/Products; Chemical Exposure and Hazards; and Chemical Effects. This subject catalog might be easily modified or adapted for use as a keyword index to CRGS. The contractor selected to implement CRGS should be cognizant of Metrek's efforts in this area.

5.0 IMPLEMENTATION OPTIONS

5.1 Public Versus Private Data Base Development

One of the problems which has been identified in the data base community is the role of the government in developing and providing information services versus the role of the private or commercial sector. To date, there has been no statement of policy for Federal agencies to follow in developing information systems. The problem grows more complex when information systems are designed which are not solely for internal government use but which have application and marketing value to selected audiences in the public sector. The U.S. National Commission on Libraries and Information Science (NCLIS) addressed this issue, among others, in its final report released in March 1975. Defining information as a natural resource, NCLIS urged the integration of the private sector into the effort to make information available to the general public.[1]

Since several of the implementation options for a CRGS involve the participation of the commercial sector, it was deemed appropriate to briefly outline some of the relevant issues.[2]

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[1] U.S. National Commission on Libraries and Information Science. A National Program for Library and Information Science - Final Draft March 10, 1975. p. 76.

[2] A list of sources used as background for the discussion appears in Appendix D as the Bibliography.

Competition - The obvious danger of the government entering the marketplace in competition with the private sector has other implications. Not only are there grounds for unfair competitive practice and intervention, but there is the possibility that data bases previously developed and offered by the private sector might be subsequently withdrawn. To a degree, the impetus for research and enhancement which have often furnished incentive to the private sector are discouraged. Furthermore, the development of high quality products has been partially attributed to competitive efforts. Economically speaking, the proliferation of government services contributes to the erosion of the general tax base.

Marketing - Closely related to the issue of competition, is the aspect of marketing. In the public sector, to "market" or create an awareness of a "product" demands some kind of public relations effort which is paid for by the taxpayer. More basic is the lack of experience the government has in marketing. The private sector is dependent on its ability to reach people directly and quickly, and therefore has a proven expertise in this area. Cost-effectiveness should not be the only criterion for the management policy of information; it is essential to reach the user community, educate, and train them in order to promote the maximal use of information systems.

Ownership - Often cited as a problem is the question of who owns, and is responsible for, the data base. If the information is produced with public funds, then presumably the government may exercise its rights of ownership. The means of access to information, however, may reside with another party and it must be considered how transferable that aspect is. Operation and maintenance of an information system is often better accomplished by a nongovernmental source since in cases of non-performance, for example, the government would have no means of penalizing itself. If public funds are employed to develop a data base, then perhaps the cost to the user would be based solely on current operating costs. Information is a valuable commodity and as such, it costs money. Regardless of whether it is publicly or privately maintained, if information fills a need and the cost is reasonable, the price will be met.

Coordination - It is important for the government to exercise a role in the development of information systems which meet its own requirements in order to curtail the duplication of services within the government, and to encourage the cooperative and optimal use of information as a national resource. While competition in the private sector is an accepted and desirable practice, competition within and among government agencies may easily result in redundant efforts and the waste of public funds.

Copyright - One alternative plan might involve the government in the "purchase" of input from a commercial source. For example, one or more of the services discussed in Section 4.0 might be subscribed to in order to tap their data-gathering operations and to establish a composite, but restructured file. While this may on the surface appear to be an attractive proposal, it presents many problems, the most significant one being the issue of royalty payments for the use of commercial data. Since presumably distribution would be broad-based, a fair, compensatory system would have to be devised. Would it be based on the number of subscribers to the "new" data base, or would it be based on each time a particular data source was used? In addition, the subscription fees to one or more of these services would increase the operational costs, and possibly, the end costs to the user. Since the data would require some restructuring or reformatting, this alternative would probably turn out to be the least cost-effective and the most cumbersome.

Certainly there are many issues to be resolved and decisions to be made regarding public support for private data bases. If the government is to encourage coordination in the development of information handling systems, and if that coordination somehow contributes to the "public good," than there seems to be some justification for government support in this area. It may be further acceptable if the government does not finance operational costs, but only supports those costs related to data base development. If the user were responsible for the operational costs, the commercial sector would not have such a sizable investment in achieving a financial return. Thus the costs to the user might theoretically be relatively low.

5.2 Plan I - Capitol Services, Inc. (CSI)

CSI's expertise lies in their familiarity with the Federal Register; their experience in and ability to write informative, keyword abstracts; and their proficiency in achieving a same-day turn-around time in their printed version, and a weekly update in the on-line file. It should also be noted that CSI furnishes the Congressional Record Abstracts data base on a daily basis for SCORPIO, the on-line system of the Library of Congress. Similarly, they provide in-house legislative services for several Federal agencies, such as DOD, DOE, HEW. Current awareness thus is adequately assured. Since CSI holds 1½ years of the Federal Register in machine-readable format, conversion to another record format could be easily accomplished.

Work Plan

Based on the preceding description of CSI's capabilities, there are a series of tasks which wuld be required to augment the CSI system in the development of a CRGS:

- Establishing a uniform record format
- Extracting from the existing file (from January 1977 to the present) of those relevant laws and regulations.
- Collecting the "backfile" (prior to January 1977) of regulations and laws.
- Collecting relevant court decisions, state laws and regulations, and government standards.
- Indexing of document items to include chemical names, synonyms, CAS Registry Numbers, and use/application codes (the latter might be unnecessary if it were determined that keyword abstracts were acceptable).
- Building the file for retrieval in an on-line operation.

The collection and processing of other source documents, such as international regulations and standards, have been relegated to a secondary level of priority. Once CRGS became operational, these would presumably be collected, processed, and added to the existing file.

Time-Phase Development

Given the tasks enumerated above, and given the efficiency under which CSI operates, CSI estimated that implementation of a CRGS, preceded by presentation of a detailed design, could be accomplished within twenty months. Table 5-1 is indicative of the time frames necessary to undertake an implementation plan based upon CSI's capabilities.

User Access - Hardware and Software

The data gathering and processing requirements outlined above are straight-forward operations with which CSI is well equipped to supply. To provide access to a CRGS data base in an on-line mode, CSI would supply tapes in the specified format to an on-line supplier, such as SDC or Lockheed, or to whomever was designated as the data base manager for CSIN. CSI would also supply back-up hard copy on demand.

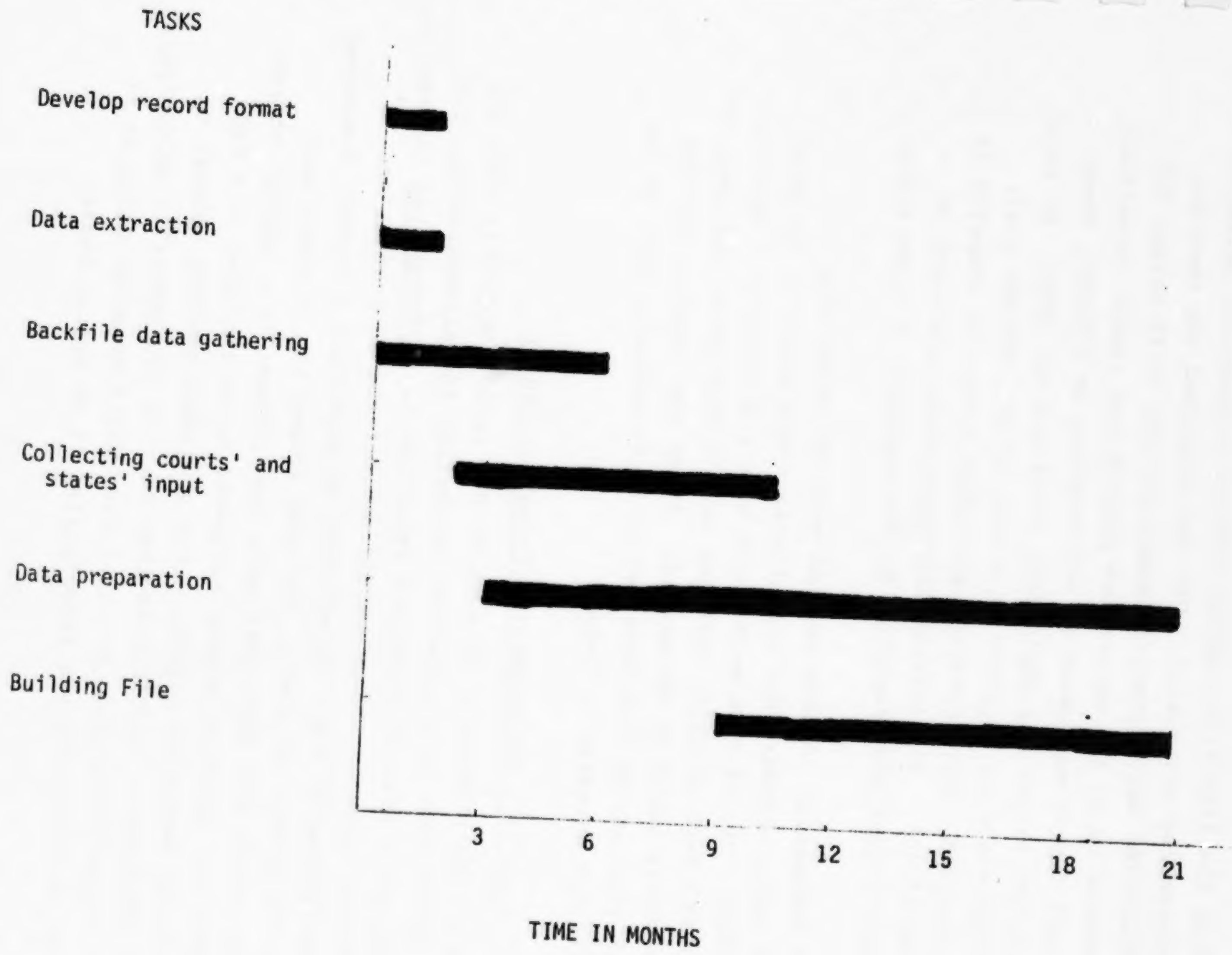


TABLE 5-1

CSI Time-Phase Work Plan

Estimated Resources (Personpower, costs)

Building the file will require certain information gathering and processing activities. CSI has estimated the need for two full-time abstractors/indexers and one staff person for two months to do the extraction program and record formatting. The cost for 3½ man years is estimated to be $70,000, based on $20,000 salary and employment costs per man year. An input operator would be required at a cost of $13,000 per year. The overhead, contingencies, and other costs are computed at a rate of 40%. The figures discussed above are based on 20 months work and therefore do not represent a fixed price.

If a commercial on-line service were to market the data base, software and operational costs would be absorbed by them. Or, if CRGS were to be made available on a national network, such as CSIN, software development costs and computer time costs would be encumbered. Since the location and the configuration of CSIN have yet to be determined, some of the costs are necessarily vague.

5.3 Plan II - Environment Information Center

One of the primary advantages of EIC is not only that they are oriented towards information collection and dissemination, but that their area of focus and expertise is environmental information. However, they do not presently monitor the activities and regulations of FDA. In addition to providing a current awareness to the source documents, EIC also stores the original hard copy which they make available upon request at a nominal charge. Given the kinds of source documents to be included in a CRGS and the necessary currency, EIC considers monthly updates to be sufficient. EIC stated that they do not generally participate in competitive bids, but that they would consider doing so if the contract were not renegotiated on an annual basis.

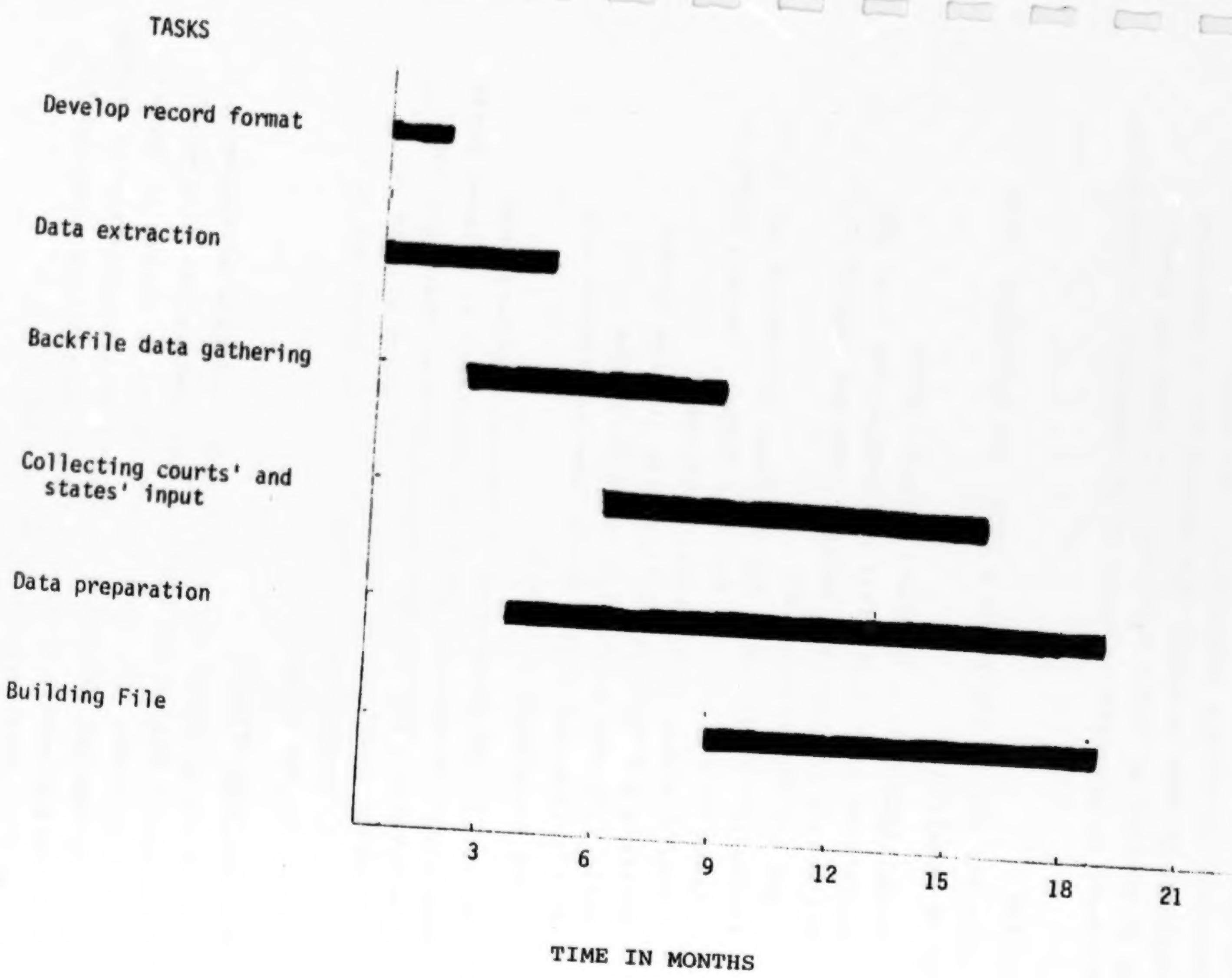


TABLE 5-2

EIC TIME-PHASE WORK PLAN

ENERGYLINE and ENVIROLINE, their two on-line data bases, are available through commercial suppliers, SDC and Lockheed respectively. EIC also has an in-house computer which could be converted to on-line processing. All manuscript and data preparation is done in-house also except for keypunching which is handled by their supplier. EIC also has great proficiency in abstracting which is an important consideration.

Work Plan

In order for EIC to implement a CRGS, the following tasks would be required:

- Establishment of a document record format
- Extraction of Federal laws and regulation from ERH
- Collection of pre-1972 Federal laws and regulations, and all FDA regulations
- Processing of document records from the second and third tasks to include CAS Registry Number, Subject Headings and/or short, informative abstracts
- Building a computerized file with on-line access
- Collection and processing court decisions
- Abstracting and coding state laws and regulations, and government standards

The collection and processing of Federal standards and international regulations would be undertaken in a later phase of development. EIC has also estimated that there are 100 environmental court cases per month, of which all are not necessarily "significant." They feel this would not be a difficult source to monitor.

Time Phase Development

Since EIC feels there would be minimal software development, the resources needed for building and testing the file would not be extensive. The full period needed to create an operational system was estimated by EIC to be approximately 18 months. Table 5-2 represents a gross estimate of the time involved for each of the tasks enumerated in Section 5.3.1.

User Access - Hardware and Software

Similar to CSI, EIC would supply tapes in the specified format to the on-line supplier, as well as provide the back-up hard copy.

Estimated Resources

As in the case of CSI, the source document collection and processing require the greatest amount of effort. While they already have the state regulations and laws in-house, those items must be converted to the standardized format. Extensive review of Title 21 of the Code of Federal Regulations, which is Food and Drugs, would also be required since that area is not presently monitored. Given the tasks outlined above, two full-time abstractors/indexers are needed, and one information specialist and/or project coordinator and an input operator, each for 12 months. The services of a programmer/analyst would be required for only two months. Based on an 18 month schedule, the total cost of personpower is estimated at $120,000. EIC estimates computer costs, which are actually input costs, on a per unit basis. Given that, the initial input was approximated by EIC to be 3000 records, at $10 per record, or $30,000. Their overhead is estimated at 30 percent. (These estimated costs do not include maintenance and update).

5.4 Plan III - Information Handling Services (IHS)

As evident from Table 4-1, IHS collects all four primary source documents, however, these sources are all updated with varying frequencies. Full text of all sources is available on microfiche, and the indexes direct the user to the appropriate location in the source document. It should also be pointed out that the indexes for each of the primary source documents do not necessarily possess identical terminology since each is issued as a separate product. Since IHS is a large firm, one advantage would be their present in-house capabilities which could assist in the development of a CRGS.

Work Plan

Since IHS already maintains a good retrospective collection of the source documents in full text, there would be a minimum amount of "backfile" data gathering. The tasks remaining would include:

- Establishing a uniform record format
- Extracting the relevant portions from the Statutes at Large, Federal Register, U.S. Reports, and State Session Laws
- Collecting documents from the U.S. Court of Appeals (D.C.), the Circuit Courts, and the U.S. District Courts
- Collecting the most current update material to the primary sources
- Converting the source document material to the established record format
- Developing a comprehensive indexing terminology from their own individual indexes
- Building the file in an on-line search and retrieval mode

It must be stressed that IHS does not maintain as current a file as required by the nature of a CRGS. Obviously microfilming the original publications is not conducive to a rapid turn-around time. Thus, it would be necessary for IHS to initiate some mechanism prior to microfilming which would provide immediate input into the CRGS file.

Similarly to CSI and EIC, the collection of secondary sources, such as international regulations, would be relegated to a later phase of development.

Time-Phase Development

IHS did not consider it appropriate to establish a time-frame for the completion of each specific task, however, they did state that a CRGS could be operational within two years, and conceivably several months less.

User Access - Hardware and Software

IHS presently maintains an on-line retrieval capability, however, it is for in-house use only by an information specialist and is not available to the public. Certainly on-line access to a CRGS would require considerable software development. IHS could supply copies of the full text documents upon request since all source documents would be available on microform.

Estimated Resources

It is IHS' policy not to quote any cost figures unless they have a very precise definition of the system requirements. In addition, they compute a different overhead for each job, depending upon the internal and external resources which must be employed. They are a large, diversified company, and it is probable that many of the skills and human resources needed for the development and maintenance of a CRGS are already directly available to them.

5.5 Plan IV - Development of a Public Data Base

While there is strong evidence and support for the enhancement of a commercial service to meet the requirements of a CRGS, there are also some concerns about planting public monies into profit-making orgainzations (Section 5.1). In order to provide the full range of implementation options, Sigma Data developed a work plan and estimated the resources necessary for a wholly public data base. The general design employed is based on the system presented in Section 3.0

Work Plan

The specific requirements of data collection have already been discussed in Section 3.2. However, the first phase of data gathering might be assisted by the use of JURIS to identify many of the source documents for court decisions and federal statutes. Search requests may be submitted to JURIS by another Federal agency. In addition to procuring a search in the JURIS data base, the tasks involved would consist of the following:

- Collect relevant Federal statutes from 1975-present
- Collect relevant Federal regulations (scanning CFR and FR titles assuming these have not yet been incorporated into JURIS)
- Identify and collect relevant state laws and regulations
- Identify and collect relevant international regulations and Federal standards
- Establish uniform record format
- Adaptation of Auerbach Classification Scheme
- Indexing and processing of source documents
- Build data base for retrieval in an on-line mode

One aspect of JURIS which must be reiterated is the ability to retrieve the full text of documents in the file and have them printed off-line. This would curtail the need to search out the citations since the text would be available.

Time-Phase Development

The first three tasks could proceed simultaneously, along with the request for, and processing of the initial JURIS search. The fourth task which is relegated to the second phase of data collection, would begin once the collection of the primary source documents had been completed. It is estimated that the implementation of a CRGS, under this option, would require eighteen months, as shown in Table 5-3.

User Access - Hardware and Software

If the government is to develop a public data base which will be part of the CSIN, hardware and software considerations are dependent upon which system is to be used.

It is important that on-line access be carefully thought out in order to make CRGS compatible with the primary CSIN files, the CDBD and the CSNS. As discussed earlier (Section 3.4.3), the data linkages to those components shall be the CAS Number, chemical name and a subject classification vocabulary. However, until the final network design is developed, the mechanism for physically integrating CRGS cannot be specified. Regardless, however, the development of CRGS should proceed in a modular fashion, using ANSII standard code (Cobol or Fortran) wherever possible, in order to facilitate transfer from one computer system to another.

Estimated Resources

Building the data base will require a similar staff for information-gathering and processing as defined by the other implementation options. This includes two full-time abstractors/indexers; one systems analyst/programmer and an input operator each for twelve months; and one project coordinator/information specialist for eighteen months. This is an equivalent of 6.5 man-years level of effort. Software costs and data collection costs were included in the total estimated cost of $210,000.

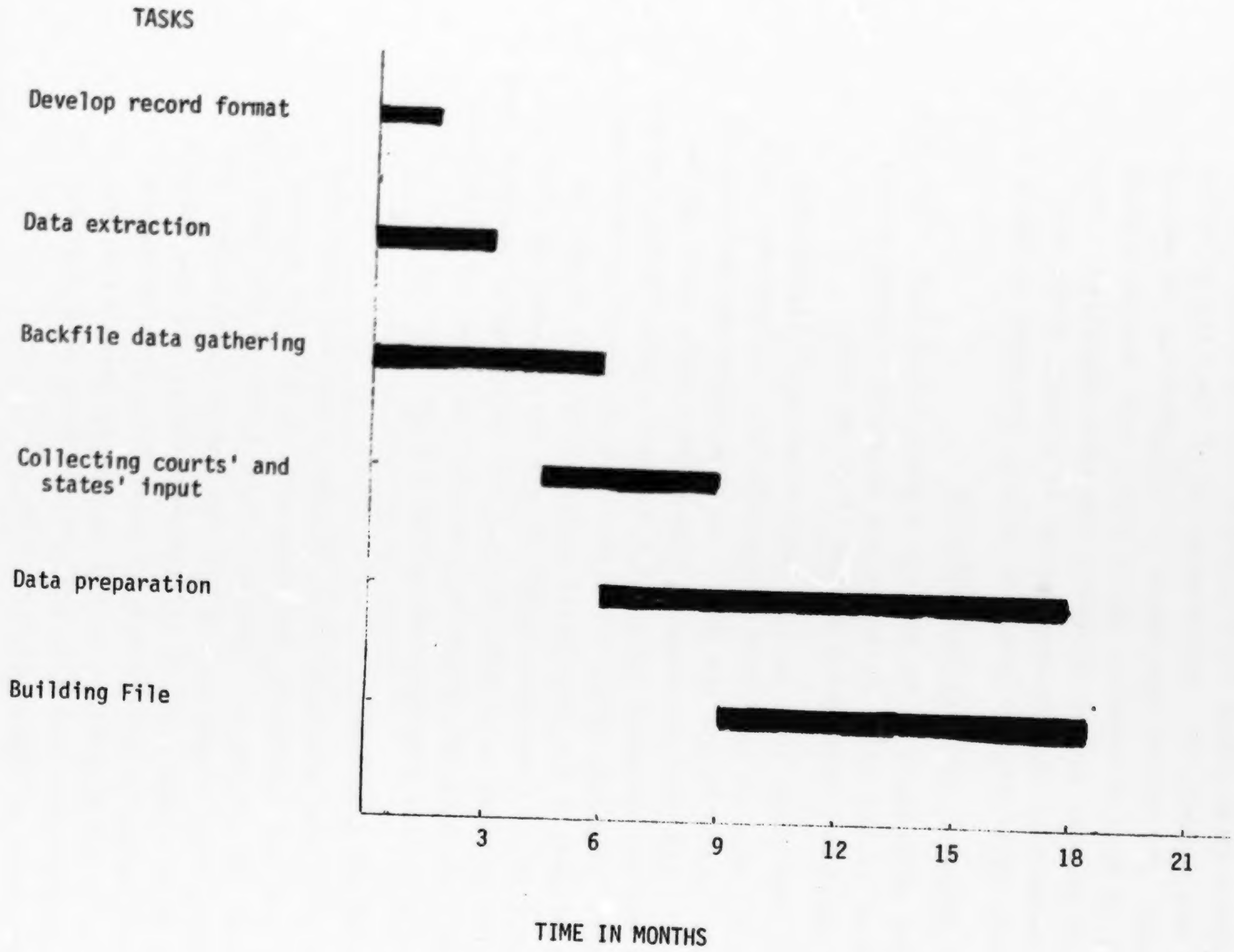


TABLE 5-3

Public Data Base Time-Phase Work Plan

5.6 Data Collection Option

One alternative plan which applies to all the options discussed in the preceding sections is the use of JURIS in the initial stage of data collection. Since JURIS encompasses many of the source documents in a machine-readable format (see Table 4-1), these could be rapidly collected for processing. Output from JURIS is available in three formats, of which two would be of assistance: a list of citations to laws and cases; or, the full text of retrieved citations. Certainly a broad search strategy would be employed using the West Publishing Codes and selected keywords, however, there is no doubt it would greatly facilitate the data collection operation. A search request for the JURIS data base is preferably initiated, however, from a Federal agency.

5.7 Plan Evaluation

Sigma Data has discussed the implementation of a CRGS with all of the services mentioned within Section 5.0. Any one of these systems has sufficient existing capability and potential to serve as a good basis for CRGS. While one existing service may have less than another in terms of present capabilities, in a bidding situation that might not necessarily serve as a decisive factor. Therefore, it must be understood that an investigation of existing capabilities cannot provide a definitive decision on a single method of implementation. Sigma Data has, instead, selected those services which would seem to be most effective and efficient in developing an implementation strategy. A summary of the advantages and disadvantages of the existing systems is presented in Table 5-4. In addition, the following conclusions may be drawn:

COMPARISON OF IMPLEMENTATION OPTIONS

TABLE 5-4

	Level of Effort (Man-years)	Estimated Cost	Time	Advantages	Disadvantages
CSI	3.5	$183,540	20 mo.	current monitoring of FR abstracting expertise frequent updates free-text search capability existing hardware for batch operation back-up hard copy available	requires extensive backfile data-gathering and monitoring of new sources broad subject categories no chemical-specific index (other than free-text)
EIC	6.2	$195,000	18 mo.	current monitoring of FR, some court decisions, state laws and regulations frequent updates narrow focus in environmental area for subject expertise controlled subject vocabulary abstracting expertise	no chemical-specific index to laws and regulations does not presently monitor FDA
IHS	——	——	24 mo.	in-depth index for CFR wide source document coverage back-up hard copy available diverse in-house expertise	coverage not limited to target area, but coverage of entire FR, CFR considerable lag time no abstracting capability vocabulary not uniform across kinds of source documents microfilm format extensive software development for batch and on-line access
PUBLIC DATA BASE (with JURIS)	6.5	$210,000	18 mo.	frequent updates basic source document coverage from JURIS complete ownership and control by gov't full text of sources generated	public vs. private data base factors (Sec. 5.1) requires gov't maintenance and management builds an entirely new system ignoring existing capabilities

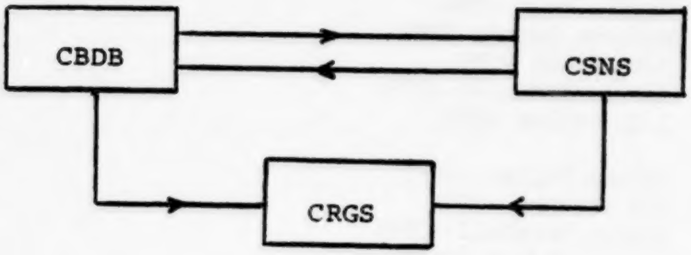
- Use of JURIS as a data gathering mechanism, regardless of the specific implementation option, would facilitate the development of a CRGS.
- Abstracts accompanying citations are extremely useful and assist not only in providing actual information but have the dual function of furnishing a measure of relevance of the item to the user.
- All records created for the file, regardless of implementation option must be examined and assigned a chemical name identifier and a CAS Registry Number or National Drug Code. At the same time, however, great care must be exercised in "interpretation" of the chemical substance or product name identification. It is absolutely essential that the intent of the law to regulate by generic name, for example, not be circumvented by assigning other "preferred" category names which might misrepresent the law.
- Establishing CRGS in an on-line mode immediately will promote greater utility and produce a measure of compatibility and availability with other CSIN core components.
- Keyword access and free-text searching of the abstract will offer the greatest flexibility to the user.
- Based on the estimated figures submitted by the existing services, development of a CRGS - not including maintenance and update - can be accomplished at an estimated cost of $210,000.
- A CRGS can be fully operational within two years.

With the definite and widening interest in chemical regulations, Sigma Data submits several recommendations:

- Steps be taken to implement a CRGS as soon as possible since the "backfile" will continue to grow and there is an immediate need.
- Development of a current awareness or tracking system among the IRLG agencies to monitor their respective internal activities.
- Implementation of a CRGS be divided into three phases: the first would give initial priority to federal laws and regulations, the second would focus on court decisions; and in the third phase, international regulations and government standards would be added.
- When funding makes it feasible, the support for the Environmental Reports Summaries should be renewed. This was the only existing, formal mechanism which served as a focus for the collection of foreign and international rulemaking activity and policy formulation.
- Consideration for use of the Auerbach Classification System as a dictionary of terms for the indexing of source documents (with the necessary enhancements), or modification or adaptation of the CDBD subject categories.

5.8 Compatibility With the Chemical Substances Information Network (CSIN)

According to the recommendations in the Mitre Report, the core components of the CSIN should be structured with some regard for standardized data elements in order to facilitate and maximize network linkages. Thus, the use of the CAS Registry Number should be vigorously enforced as well as coordination with the CDBD and the CSNS. The CDBD will catalogue and describe which data bases contain information on specific subjects via a locator device. The CSNS will provide complete identification information on a chemical substance, and will indicate which data bases contain information about chemical substances via a locator device. A possible schema for the interface among these data bases is depicted below:



This is not intended to preclude the interface of other CSIN components which may have relevance. CRGS must be considered a functional component of CSIN even though the "position" it will hold in the network configuration still remains to be determined. As has been pointed out in previous studies, users generally will require access to more than one component of CSIN in order to satisfy their data needs. It is essential that the developer of CRGS, whether it be from the public or the private sector, keep the requirements for compatibility in sharp focus.

APPENDIX A

INTERVIEWS

FOR THE CHEMICAL REGULATIONS AND GUIDELINES SYSTEM

EPA: Marilyn Bracken (OTS)
Elbert Dage (OTS)
Warren Muir (OTS)
Barbara Ostrow (OTS)
John Ritch (OTS)
George Semenuik (OTS)
I.E. Wallen (OTS)

Sandra Fuller (OPP)
Ann Hoffnar (OPP
Robert Marshall (OPP)
Lowell Miller (OPP)

Carol Alexander (UNEP)
Henry Beal (Standards and Regulations Office)
Carol Ditzler (EPA Library)
Irving Fuller (Office of International Activities)
Lillian Hibbs (EPA Library)
Charlene Sayers (UNEP)
Morris Yaguda (MIDSD)

FDA: Ed Allera
Winston Cobb
Al Gelberg
Ted Herman
L. Robert Lake
Mary McEniry
Phil Paquin
John Richards
Ralph Stafko
Ron Wylie

OSHA: Pat Breslin
Bob Kluck

CPSC: Bill Bercaw
Chuck Casper
Terry Kuch
Steve Lemberg
June Thompson
Irvin Weiss

APPENDIX A (Continued)

NCI: Office of Cancer Communication

NIOSH: Nelson Lidel

OTHER: Environmental Defense Fund, Toxic Chemicals Program - Marcia Fine
International Association of Heat and Frost Insulators and Asbestos Workers - Roy Steinfurth
International Chemical Workers Union - Larry Ahearn
Manufacturing Chemists Association - George Ingle
Synthetic Organic Chemical Manufacturers Assoc. - Ronald Lang
United Steelworkers of America, Dept. of Safety and Health - Adolph Swartz

Capitol Services Inc. - (CSI) 511 Second Street, N.E., Washington, D.C. 20002	Wayne Muhlstein
Environment Information Center (EIC) 53 D Street, S.E. Washington, D.C.	Sharon Schatz Karen Ziegler
Bureau of National Affairs, Inc. (BNA) 1231 25th Street, N.W. Washihgton, D.C. 20037	Girard L. Ordway
Information Handling Services P. O. Box 1154 Englewood, Colorado 80110	William Shannon John Dann Robert Williams Stephanie Prigge Eugenia Greenfield
JURIS Dept. of Justice Washington, D.C.	Richard Chagnon Page Basheer

APPENDIX B

REGISTRATION/MONITORING/ENFORCEMENT SYSTEMS

APTIC	a bibliographic file of books, journals, and report literature in the area of air quality information. Federal litigation and enforcement actions as reported are included. (EPA)
ASTRO-4 DRUG INFORMATION SYSTEM	a file of data on New Drug Applications (NDAs) and Investigational New Drugs (INDs). The data include drug manufacturers, drug names (trade, generic, chemical), drug usage information, pharmacological activity, route of administration, and status of drug applications. (FDA)
COMPLIANCE DATA SYSTEM	stores, updates, and retrieves data describing the compliance status and enforcement activity of the sources of stationary air pollution. The output includes an inventory of facilities emitting regulated pollutants, an assessment of enforcement strategies, and measurement of compliance and enforcement progress. (EPA)
DRUG REGISTRATION AND LISTING SYSTEM	maintains data files on drug establishments registered with FDA and all product data submitted by drug firms relative to the Drug Listing Act of 1972. In addition to human drugs, it includes biologicals, in vitro diagnostic products, and veterinary drugs. CAS Registry Numbers for ingredients can be related to their preferred ingredient names. (FDA)
PESTICIDES ENFORCEMENT MANAGEMENT SYSTEM	maintains a nationwide record of pesticide samples collected, violations detected, and enforcement actions taken. Such data is used to determine penalties and to formulate sampling strategies. (EPA)

APPENDIX F (Continued)

PESTICIDE PRODUCT INFORMATION SYSTEM	an inventory of registered and pending pesticide products which includes the manufacturer's name and address, product name, active chemicals and their percentages, and the use pattern for which the product is registered. (EPA)
PESTICIDE REPORTING SYSTEM	gathers information on the examination of official and investigational samples of pesticides to detect pesticide residues and their association with food products at the point of origin. (FDA)
TECHNICAL DATA CENTER	a collection of the journal and technical report literature from worldwide sources in the area of occupational safety and health. Its 60,000 documents support standards development activities. (OSHA)

APPENDIX C

PERIPHERAL COMPLIANCE SYSTEMS

PREDICASTS - FEDERAL INDEX

The Federal Index is available on-line through Lockheed's DIALOG. It provides coverage of proposed regulations, and those in effect, the Congressional Record, Presidential Documents, and the Washington Post. Entries are indexed according to SIC (Standard Industrial Classification) codes and include a citation with a very brief comment. Free-text searching is also available. Its coverage is from October 1976 to the present and updates are conducted monthly. Document delivery is available at a nominal charge.

SIC codes are assigned to companies by the Office of Management and Budget to indicate the principal products manufactured or the major services furnished. The categories are extremely broad: Chemicals and Allied Products; Rubber and Miscellaneous Plastic Products.

SUMMARIES OF FOREIGN GOVERNMENT ENVIRONMENTAL REPORTS

This project, funded by the Office of International Activities - EPA was a monthly publication of citations and abstracts of foreign government documents in various subject areas such as air, water, noise, solid waste, pesticides, toxic substances, radiation, and land use. Fifty countries and nine international agencies are represented in the compilation. The project was begun in the early 1970's and terminated in Dec., 1977 due to lack of funds. There is a cumulative index through June, 1976 which has entries by country and subject. EPA maintains the original documents, but the collection is copyrighted and for reference use only.

RTECS - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

This is the on-line version of the publication with the same name, formerly known as the Toxic Substances List. It is compiled by the National Institute for Occupational Safety and Health as mandated by PL 91-596. RTECS includes toxicity data for an estimated 21,000 substances with approximately 60,000 synonyms. The data elements most relevant to a CRGS are:

APPENDIX C (Continued)

- Threshold Limit Values - recommended limits proposed by the American Conference of Governmental Industrial Hygenists
- Standards and regulations - OSH Act of 1970; substances regulated by DOT; FIFRA; US Occupational Health Standard
- NIOSH Criteria Documents - 218 records taken from 45 criteria documents
- Status - EPA - if selected for study as a water pollutant; NCI - if being tested as a carcinogen by standard bioassay.

All these are searchable data elements and it should be also noted that synonyms are searchable by the first 39 characters.

RTECS is updated on an annual basis, usually as soon as possible after the machine-readable edition is received from NIOSH.

APPENDIX D

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Williams, M.E., "The Impact of Machine-Readable Data Bases in Library and Information Services," *Information Processing and Management* 13 (2): 95-107. 1977

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